# Stents, Smart Stents and Their Importance for Wireless Biomedical Applications

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***Abstract*—A stent is a renowned choice for treating coronary artery disease and other diseases related to artery or vessel blockages. It is a meshed, tube-like supporting scaffold inserted into arteries or vessels where blood flow has become critically restricted to restore normal blood flow. The progressive success of stents has led to the emergence of wireless smart stents. They integrate sensors to perform wireless monitoring of the artery or blood vessel for any obstruction of the blood due to in-stent restenosis (ISR). Additionally, the wireless interface also assists in the wireless powering of the stent. The therapeutic uses of smart stents to cure ISR, explored by many research groups, are also discussed. Particularly, we focus on different types of sensors and wireless technologies used for sensing and wireless transmission of arterial health and overview the limitations of various sensing and wireless technologies of smart stents. Finally, the emerging future technologies that are envisioned to improve present smart stent technology is reviewed.**

***Index Terms*—Stent, stentenna, smart/active stents, pressure sensors, bare metal stents (BMS), drug-eluting stents (DES), bioresorbable stents (BRS), balloon angioplasty, balloon expandable stents, thermally expandable stents, self-expandable stents, wired stents, tubular stents, modular stents, smart stents, Coronary artery disease, Peripheral arterial diseases, Esophagus, bile duct, Aneurysms, EVAR, hyperthermia, ablation.**

## I. Introduction

GLOBALLY, coronary artery diseases (CAD), peripheral artery diseases (PAD), esophageal cancer, biliary obstruction, and aortic aneurysm are caused by the obstruction of blood and other fluids in different arteries, blood vessels or other passages due to restenosis or other substances, leading to the death of millions of people [1], [2], [3], [4]. To keep the artery or blood vessel open, a small tube-like structure known as stent is implanted, it resumes the flow of blood or other fluids in CAD, PAD, esophagal cancer, biliary obstruction, and aneurysms [5], [6], [7], [8]. Although a stent helps to open a blocked artery or other passages, there is a tendency for re-narrowing due to the development of in-stent restenosis (ISR). Drug-eluting stents (DES) were introduced in 2002 to reduce the possibility of in-stent restenosis. In the DES, the stent's stainless-steel platform is coated with a drug-eluting, durable polymer [9]. DESs could help to overcome the growth of ISR to some extent, regardless of the upgraded biocompatibility, inflammation and early neoatherosclerosis could not be overcome with drug-eluting stents [10]. Furthermore, extensive research in the stent technology to overcome the likelihood of ISR has resulted in numerous stent design patterns and fabrication technologies, such as wired stents, slotted tube stents, and modular stents, are discussed in this review [11], [12], [13]. Different expansion mechanisms of stents such as balloon expandable, self-expandable, and thermal expandable, have also been developed to reduce the formation of ISR are discussed in Section II; in this review, we have explained briefly their limitations and advantages in terms of ISR [14], [15], [16]. Despite all these efforts, there is no way to stop the growth of ISR. In an extensive study conducted from 2002 to 2016, the percentages of reappearance of ISR after a first, second, and third percutaneous coronary reintervention (PCI) were 8.3%, 17.1%, and 22.8%, respectively [17]. Therefore, further technological developments can reduce mortality by assisting the patient with a timely diagnosis and preventing delayed treatment, leading to the development of smart stents.

Smart stents have an integrated sensor and a wireless interface for sensing and continuously monitoring ISR, as well as wireless powering for the stent. In literature, many research studies have attached MEMS capacitor pressure sensors to the stent to detect ISR by measuring blood pressure. The MEMS capacitor and the stent form a resonant circuit, and the resonant frequency changes due to the changes in capacitance, indicating that some obstruction is present [18], [19]. However, a few researchers have also proposed ultrasonic and bioimpedance sensors to detect obstructions in the blood or other fluids of coronary arteries or other passages. Data and power telemetry are also crucial for transmitting sensor data related to the arterial or blood vessel's health wirelessly to the external monitoring device.

Some research groups have converted stents into therapeutic devices by enabling the heating feature in the stents to cure ISR, which is a noninvasive method categorized into resonant and inductive heating, which is discussed in Section III. Section IV discusses safety considerations in smart stent's designing; Section V discusses smart stents limitations. Sections VI and VII discuss clinical translation barriers in smart stent designing and future scope by discussing possible ways to improve smart stent technology. Finally, Section VIII concludes the review.

## II. Conventional Stents

This section provides a brief overview of the conventional stents.

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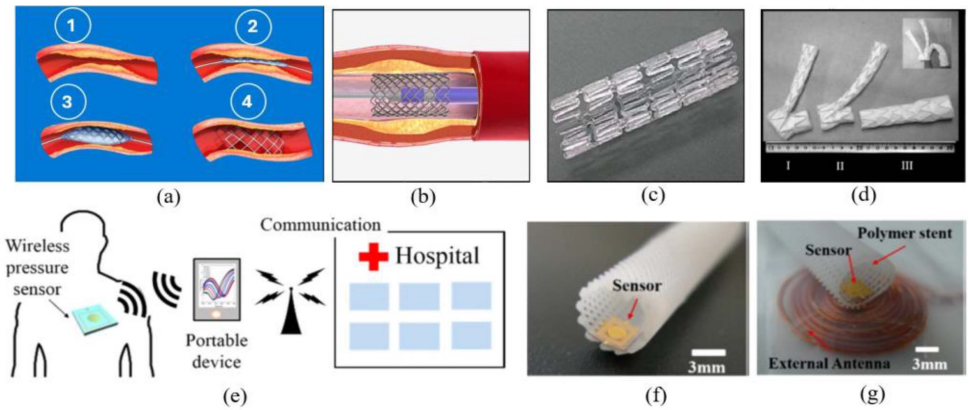



Fig. 1. (a) Stenting using balloon angioplasty [30], (b) wired stent [31] (c) slotted-tube stent [32] (d) modular stent (I to III are different sections of the modular stent, and the complete stent, by connecting all three parts, is shown in IV) [33] (e) Wireless pressure monitoring using a pressure sensor-integrated stent; (f)–(g) 3D-printed polymer stent with an integrated pressure sensor [33].

### A. History of Conventional Stents

Until the 1980s, balloon angioplasty was the only procedure to open obstructed arteries. Dotter and Judkins first explained the concept of coronary balloon angioplasty in 1964; however, Andreas Gruntzig experimentally performed the procedure in 1977 [20]. Balloon angioplasty resolved the issues of blocked arteries but the re-narrowing of the arteries owing to acute vessel closure caused by elastic recoil and artery perforation were the main issues [21], [22]. Consequently, bare metal coronary stents were developed to avoid the complications of balloon angioplasty by holding the balloon-dilated artery in a fixed position and avoiding artery recoil, as shown in Fig. 1(a). Schatz and co-workers developed the first balloon-expandable, stainless steel, slotted tube-like FDA-approved stent in the USA in 1987 [23].

### B. Types of Stents

*1) Bare Metal Stents (BMSs):* Early BMS were built from corrosion-resistant stainless steel materials of high elastic modulus, yield, and tensile strength, offered satisfactory radial strength to scaffold the vessel and prevent recoil [24], [25], [26]. Owing to its mostly iron composition, stainless steel is not MRI-compatible and had thicker strut [25], [27]. Next, cobalt-chromium alloy and platinum-chromium metal stents, which have thinner struts and better radio-opacity and radial strength owing to higher density, elastic modulus, yield, and tensile strength were constructed [28], [29]. Despite using different approaches ISR rates were high.

*2) Drug-Eluting Stents (DESs):* The year 2002 the first generation of DESs with a stainless-steel platform coated with a drug-eluting durable biocompatible polymer were introduced, to prevent ISR [9]. The first-generation DESs compared to the BMSs, needed-long-term antiplatelet therapy to avoid ISR, which can cause thrombosis [34]. This issue was resolved in second-generation DESs by using cobalt-chromium and platinum-chromium alloys for stents because they can be manufactured with a small strut thickness, which helps to reduce thrombosis and requires comparatively short antiplatelet therapy.

An experimental study in which follow-up was after 12.3 months for DES and 11.7 months for BMS. It showed ISR rates of 18.4% for DES. and 31.1% for BMS [35]. In another study conducted on clinical data collected from 2000 to 2019 found that compared to BMS, second generation DES had a significantly lower rate of all-cause mortality 2.4% vs. 3.9%, target lesion revascularization 3.5% vs. 8.6%, and myocardial infraction 2.1% vs. 2.9% [36]. The current DES are based on more biocompatible polymers, such as polyvinylidene fluoride, hexafluoropropylene, and polyvinyl pyrrolidone [37] but inflammation and early neo-atherosclerosis could not resolved [10].

*3) Bioresorbable Stents (BRSs):* The BMS and DES reside permanently, and this can cause permanent disruption of the fine endothelial layer of the artery [38]. Subsequently, side branch blocking due to reduced conformity of the artery and chronic inflammation due to the polymer exposure in some people might happen [39], [40]. Meanwhile, BRS naturally break down and dissolve into the blood provides uninterrupted blood flow, does not require antiplatelet therapy, and eliminates the danger of persistent inflammation.

However, the performance and degradation duration of the BRS are impacted by its construction materials (polymer or metal.) The polymer stent has thicker strut, but a longer degradation time as compared to the metal stent (approximately 20 months) [41]. Whereas the faster degradation of metal biodegradable stents makes them unable to remove early ISR (formed within 18 months).

### C. Expansion Mechanisms of Stents and Their Effect on the ISR

*1) Balloon-Expandable Stents:* Balloon-expandable stents are mounted on a balloon in a contracted state, delivered at the desired location, and then deployed by expanding the balloon [14]. As the balloon expands, the stent attains its maximum diameter and holds the artery in a stable position [20]. These stents are good for hard-to-reach complex blockages. However, sometimes, the stent expansion mechanism can cause injury to the artery due to the pressure induced by balloon inflation for stent's expansion.

*2) Self-Expandable Stents:* Self-expanding stents are made of Nitinol (a nickel and titanium alloy), which is a shape memory alloy [14], [42]. These stents, after implantation in a biological environment, regain their actual shape within a few days and are easy to implant in irregular-shaped vessels and difficult-to-reach locations such as PAD and aneurysms [15], [43]. These stents are safe due to their natural expansion and causes low ISR, but can experience under expansion [44], [45].

*3) Thermo-Expandable Stents:* Shape memory polyurethane is a favorable stent material due to its flexibility in deforming and recovering its original shape. These Stents can then be crimped into a smaller form, installed on a delivery system and navigated to the problematic site of the artery, where they can finally be thermally activated to regain their initial form [46].

*4) Clinical Studies on Treatment of ISR Using Balloon-Expandable, Self-Expandable and Thermo-Expandable Stents:* In an experimental study, 14 dogs with aneurysms were treated by balloon-expandable tantalum and self-expanding nitinol stents. After nine months, balloon expandable stents showed up to 40% of ISR. However, 15% of ISR was found in self-expandable nitinol stents [47]. In a study conducted on thermos-expandable stents, the successful insertion of thirty-three stents in twenty-seven patients studied. The stenosis length was $10.14 \pm 6.76$ cm, and the hospitalization was $4.43 \pm 1.83$ days. The patency rate of patients with thermo-expandable metallic stent were 92.4% (SD (standard deviation) = 5.2%) in eight months, 77.4% (9.1%) in 12 months and 67.7% (SD = 12%) in 29 months, while the cumulative survival rate was 87.5% (SD = 11.5%) in 29 months [48].

### D. Structural Design and Fabrication Methods of Stents

Depending on the type of structural design, stents can be classified into the three categories discussed below.

*Wired stents* are formed by creating circular coils of wire to produce coil-shaped stent scaffolds, as shown in Fig. 1(b). These are flexible but exhibit poor radial force. To increase the radial force, the wire strut must remain thick, which might speed up the ISR formation [49].

*Slotted tube stents* are built from a metallic tube by laser cutting to create different patterns on the tube, see Fig. 1(c). These stents are comparatively less flexible and do not possess good deliverability due to poor side branch access as compared to the wired stents but can withstand more compressive radial force [49], [50].

*Modular stents* design is fabricated using multiple repetitions of fused modules, which are fused to realize a stent tube, as shown in Fig. 1(d). The modular stent has qualities of both wire and slotted-tube stents, such as flexibility and radial strength, side branch access, and a lower possibility of ISR occurrence [49], [51].

### E. Impact of Stent's Fatigue on Its Mechanical Degradation and Corrosion Resistance Properties

Mechanical fatigue in stents is a serious concern. It can be caused by several factors, such as stress experienced during implantation procedure due to the shape of the artery such as tapered shapes. Next, material such as Co-Cr and nitinol has high fatigue resistance as compared to stainless steel [52]. Another factor is that stent faces approximately 40 million pressure cycles from heartbeat [53]. In an in-vivo experimental study, 28 peripheral stents made of nitinol, cobalt-chromium-nickel, tantalum, V4A and different surface treatments such as electropolish, mechanical polish, and unpolished were tested [54]. A constant voltage of 3.5 V and current of 1.16 mA in 0.9% NaCl was applied to speed up corrosion. Nitinol stents showed the lowest susceptibility to corrosion and remained undamaged for the longest period and showed neither macroscopic nor microscopic damage. The cobalt-chromium-nickel stent showed ten times more damage and multiple fractures compared to the nitinol stent, whereas V4A and tantalum stents showed some fractures but less than the Co-Cr stents.

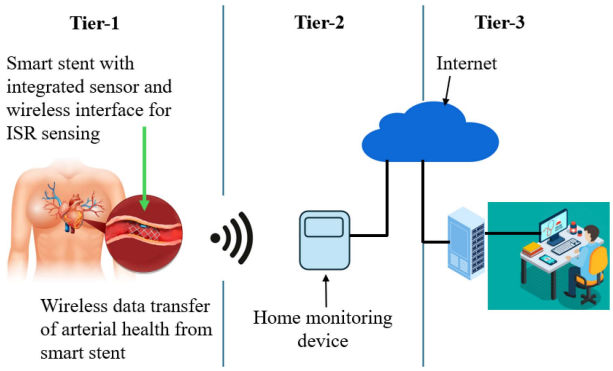



Fig. 2. A three-tier architecture of a future smart stent communication system. Tier-1: a smart stent implanted in the coronary artery. Tier-2: the smart stent communicates wirelessly to an external home monitoring device. Tier-3: the home monitoring device sends the physiological data to a remote healthcare professional [55].

## III. Smart and Active Stents

A smart stent integrated with sensors, and a wireless interface monitors the post-implantation health of arteries or blood vessels [56], [57], [58], [59], [60], [61], such as the development of ISR/vessel blockage, and transmits this data to the external monitoring device and distant doctor.

### A. Sensing Methodologies of Smart Stents to Detect ISR

*Pressure sensors* integrated inside the stent continuously monitor the pressure of blood in the artery or vessel, as shown in Fig. 1(f), (g), (h), enabling the continuous collection of physiological data and remote monitoring of cardiovascular health, [33], [59]. The data can be transmitted to an external device for analysis by healthcare professionals, as shown in Fig. 2.

*Ultrasonic sensors* monitor changes in blood flow within arteries or blood vessels that indicate the presence of ISR. Ultrasonic sensing is proposed in [56], [61], where a pair of ultrasonic sensors is integrated into the stent to sense the flow of blood to evaluate ISR.

*Bioimpedance sensors* measure the changes in electrical impedance of the arterial tissue surrounding the stent, which changes in response to ISR development [57], [58], [60]. In [57],

an electrical Impedance Tomography (EIT) system is proposed, utilizing eight electrodes placed around the circumference of the stent. This technique is non-invasive, using low-frequency electrical current to create an image of the internal conductivity distribution of an artery by measuring potential differences on the surface. In [58], sensor based on electrical impedance spectroscopy (EIS) is integrated into the stent. To identify a blocked artery resulting from ISR formation, a small alternating current signal is applied to the set of electrodes connected to the stents around the arterial wall, and the corresponding voltage or current is measured at various frequencies.

### B. Examples of Biomedical Applications for Smart Stents

*1) Post-Stent Implantation and ISR Monitoring in CAD:* In early research on smart stents, vascular stents were used as antennas for intravascular MR guidance and imaging [62]. This active stent was developed using stents as receive-only imaging probes for stent deployment because X-ray angiography, as an imaging modality, is usually inadequate in accurately assessing vessel size, plaque calcification, or metal stent deployment. This wireless active visualisation of the stent permits in-depth evaluation of the stent lumen with high contrast and spatial resolution. This study did not examine the heating and other safety concerns of the presented active stent and long-term ISR monitoring. In another research, the stent was used as an antenna for long-term ISR monitoring [63]. Here, the designed stent resonated at the Larmor frequency of the MR system. Using the inductive coupling principle, the fields of the stents were coupled to those of an outside surface coil. The stents thus acted as local RF signal amplifiers. This approach granted a convincing diagnosis for the noninvasive long-term monitoring of ISR. In this work, the metal stent was coated with a polyurethane dip coating to maintain biocompatibility and electrical insulation. A wireless blood pressure monitoring system has been validated using a micromachined stent antenna with a capacitive pressure sensor [18]. The limitation of this work is that the experimental verification of this stentenna was conducted in a non-conductive liquid, whereas in practice, blood has appreciable electrical conductivity. In another research, a micromachined stent for prolonged monitoring of intraluminal conditions within an artery, duct, fistula, or other flow path was proposed [64]. Here, in first method, a silicon-micromachined capacitive pressure sensor with a dual-inductor stentenna was used for wireless flow measurement. The second method investigates the electromagnetic (EM) detection of blood flow in a polarizable liquid. It can be applied to only polarizable liquids, including blood, and provides a more direct measurement of flow velocity that is less affected by the properties of the liquid.

A flexible and stretchable wireless pressure sensor-integrated smart self-reporting stent was proposed [19]. This pressure sensor is based on an LC circuit, where L is the inductance of the coil mounted on the stent and C is the capacitance of the integrated MEMS capacitor and displays a convincing linear relationship between variations in resonating frequency of the LC circuit corresponding to pressure changes. One more research discussed a dual inductor stentenna integrated with two micromachined capacitive pressure sensors with sensitivity mentioned in Table I [65]. Experimental results revealed that the ability for flow and high-pressure sensitivity is over 100 times better than past efforts. An early research on stent-based biotelemetry was proposed by using commercially available stents (Cook Medical, Bloomington, IN, USA) through simulations and in-vivo findings [66]. A polymer-based wireless pressure sensor developed and integrated with a biodegradable 3D-printed polymer stent is shown in Fig. 1(e)–(g) [33]. The wireless pressure sensor is a resonant circuit (formed by an integrated capacitor and a stent) and can be used without an internal power source. The capacitance variations caused by changes in the intravascular pressure shift the sensor's resonance frequency. The pressure sensor can measure pressure from 0 mmHg to 230 mmHg, with a sensitivity of 0.043 MHz/mmHg and its biocompatibility was satisfactory inside the neonatal rat body (observed for one month). In another study, a novel hybrid polymer stent consisting of polycaprolactone (PCL) and polylactic acid (PLA) that demonstrates enhanced bending flexibility and radial force was proposed [67]. This hybrid stent was combined with a MEMS-based LC-type wireless sensor to monitor blood vessel pressure changes continuously. The sensitivity of the fabricated wireless pressure sensor was 19.66 kHz mm/Hg. A novel method to fabricate sensor-integrated smart stents using the standard MEMS fabrication process is examined [68]. The stent and the capacitive pressure sensor were designed using biocompatible photosensitive SU-8 polymer on a silicon wafer and together form a resonant circuit to detect pressure changes. The pressure sensitivity was checked by applying pressure up to 250 mmHg in increments of 50 mmHg after inserting the sensor into a 4 mm tube. This sensor had a sensitivity of 1.28 kHz/mmHg, and it improved further when the entire stent was considered as an inductor. However, this study did not evaluate SAR to ensure the safety of the patients. A stent-based, fully wireless cardiac pressure sensing system based on ASIC (application-specific integrated circuit), and a MEMS capacitive sensor integrated with the Cook Medical stent was proposed [59]. This system's average simulated SAR of the three-layer tissue section with 3.2 W transmitted by an external power source at 10 cm from the chest at 3.7 GHz surface was 2.29 W/kg. The value is slightly greater than the 2 W/kg specified by both the IEEE C95.1 and ICNIRP guidelines.

TABLE I
COMPARISON OF WPT EFFICIENCY AND SENSITIVITY FOR SMART STENTS

| Ref. | Eff. | Sensing technique | Sensitivity (mmHg) | Stent type |
|---|---|---|---|---|
| [64]/ [65]/ [67] | - | pressure sensor | 0.043/1.28/0.5 | coronary |
| [79] | | Viscosity sensor | 427 ppm/cP | Bile |
| [91]/ [93] | 1.6 % /3.6 % | - | - | AAA |

SAR (Specific Absorption Rate) and tissue heating Analysis: In literature, many authors proposed different soultions for wireless monitoring of smart stents [18], [19], [60], [61], [62], [64], but very few studied SAR and tissue heating [68]. The research

proposed in [68] analyzed the SAR, which was slightly more (2.29 W/kg) than the standard limits (as previously discussed in this section)

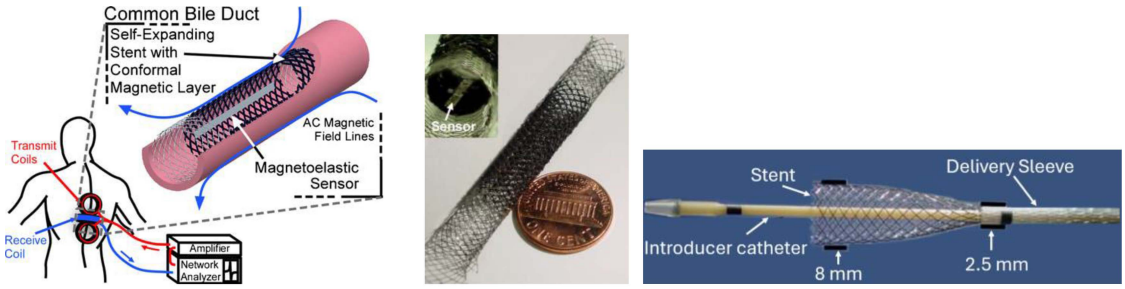
*2) Treatment of ISR in CAD:* Practically, to date, DESs are the only clinical solution to mitigate the early incidences of ISR for the first few years post-stenting. However, as time passes, these stents cause an increased risk of late ISR [69]. To create better solutions than the DESs, many researchers proposed heating treatments, such as hyperthermia. Hyperthermia is a well-known cancer treatment and can efficiently cure ISR [70], [71]. An electrothermal stent was proposed to treat ISR [69]. This stent was fabricated using a lithographically fabricated flexible capacitor strip with an inductive stent to realize a resonant circuit. This stent device is a frequency-dependent wireless heater controlled by an external RF field through frequency tuning. A conventionally designed hyperthermia resonant stent and its wireless power transmitter are demonstrated through in-vivo and in-vitro tests [71]. A new double-loop antenna is used as a transmitter to design the wireless stent-based hyperthermia system. In wireless power transfer, LC resonators are used at both the transmitter and receiver sides, aiding a maximum power transfer at the resonant frequency. An innovative stent with the piezo plates integrated into the stent along its whole length is suggested for treating ISR [72]. When an alternating voltage is applied, it results in vibrations in the small-scale piezoelectric plates. These vibrating plates prevent the deposition of fatty acids into the stent. A gold-coated medical-grade stainless steel stent is suggested for hyperthermia to treat ISR [73]. The stent works as an inductor, forming an RF resonant circuit with an integrated capacitor microchip. It works as a wireless heater, producing mild heat when the stent is resonated with a tuned RF electromagnetic field supplied by the external antenna. Mild heating treatment with a temperature not more than 50 °C leads to low thrombosis induction [74]. The in vitro and in vivo experiments show the stent's capability of heating for ISR removal. Another study also proposes a resonant stent with a circuit breaker for hyperthermia [75]. The circuit breaker is connected in series with the stent and keeps the stent temperature within 50–66 °C. It is a thermos-responsive switch in the chip that opens and closes the circuit depending on the stent temperature, stopping the stent from overheating.

A resonant heating-based revascularization of nitinol stent was proposed for ISR treatment [76]. When the blood pressure sensor detects ISR development, a high power of approximately 30 W is applied for 320 seconds to expand the nitinol stent for ISR removal further. Frequency shifting of the stent antenna enables wireless monitoring of the stent's revascularization state. In another research, inductive heating of the stent to shrink the ISR was proposed [77]. The temperature range for this procedure was maintained at 45–65 °C.

*3) Post-Stent Implantation and ISR Monitoring in PAD:* In peripheral arterial disease (PAD) affects more than 5 million adults in the United States [78]. It's primarily due to plaque buildup and blocks the blood carrying arteries from the heart to the limbs. PAD can occur in any blood vessel; however, it usually affects the legs rather than the arms. Peripheral artery stents are like mesh tubes fabricated using stainless steel or Co-Cr alloy and may have a self-expanding or balloon-expandable mechanism. A wirelessly powered implanted stent integrated with a Doppler sensor examined the effects of thigh tissue morphology and thickness changes was studied [79]. Thigh simulation models were derived from anthropometric data for individuals with PAD and power gain and SAR were determined for each change. This study shows that touch probe-powered stent systems can deliver significant power to an implant. In one research, the theoretical modeling and in vitro evaluation of magnetoelastic sensors intended for wireless monitoring of tissue accumulation in peripheral artery stents was proposed [80]. The sensors are fabricated from 28-$\mu$m-thick foils of magnetoelastic Ni-Fe alloy and conformally integrated with the stent to reduce its clotting potential.

*4) Post-Stent Implantation and ISR Monitoring in the Bile Duct:* A bile duct stent may be applied when the bile duct is blocked or partially blocked. This condition can occur due to bile duct cancer or other conditions. A stent can help relieve symptoms and allow bile to drain into the intestine for digestion. Bile duct stents can be made of plastic (polyethylene (PE), polyurethane (PU), or Teflon) or metal (stainless steel or nitinol) and help keep the bile duct open. The shape of the bile duct stent is not always straight; it can be a pigtail or double pigtail design to maintain it in a stable position. However, ISR can appear in 4–5 months due to bacterial growth on the biliary stent, known as biliary sludge. This sludge accumulates and blocks bile duct. The wireless monitoring of the accumulation of intimal tissue and sludge in a biliary stent was presented in Fig. 3 [81].

In which, a magnetoelastic resonator sensor was placed in the commercially available self-expanding biliary stent. The stent has a conformal magnetic layer (consisting of strontium ferrite particles suspended in polydimethylsiloxane) that biases the sensor. The outside-body examination module acquires a signal from the sensor implanted in a porcine carcass up to 5 cm. A smart biliary stent integrated with a magnetoelastic sensor and a permanent magnet is proposed for the wireless monitoring of biliary sludge deposition was presented in article [83]. In some other research works magnetoelastic sensor-integrated biliary stents were also proposed [84], [85], [86], [87], [88]. A self-expanding Biliary stent with a flexible wishbone-array magnetoelastic sensor monitoring was proposed [84]. A conformal magnetic layer was integrated with the stent structure to form a wireless system for sludge monitoring. In this biliary stent, the system is sensitive to viscosity changes and mass buildup, showing a 7% and 38% decrease in resonant frequency in 10 cP fluid after an applied mass load 2.3 times the sensor's mass. In a research, the in-vivo and in situ evaluation of a system that wirelessly monitors the accumulation of biliary sludge in a plastic biliary stent was discussed [86]. For the in-situ verification, the stent was positioned at various locations inside the abdominal cavity of a female domestic swine carcass to assess the system's wireless communication range. It was found that the stent was approximately 7.5 cm from a sensor array covered in bile. The in vivo testing incorporates the endoscopic implantation of a stent into the bile duct of a swine. Later, the swine was monitored for 4 weeks, and no adverse effects were found. A multi-coaxial connector antenna was proposed to treat bile duct blockage




(a) (b) (c)

Fig. 3. (a) Conceptual diagram of the magnetoelastic monitoring system used in the porcine carcass in situ experiment. (b) 8 mm×60 mm biliary stent after sensor and conformal magnetic layer integration. The inset shows a view of the stent lumen and attached sensor. The ends of the stent are masked during the conformal magnetic layer coating procedure. (c) Partially deployed 8 mm×60 mm self-expanding biliary stent (Wallstent$^{TM}$, Boston Scientific) [81].

due to tumor [89]. In this work, a novel coaxial-slot antenna working at the 2.4 GHz frequency with multiple slots near the tip was designed for effective heating along the stent. The biliary stent is heated by electromagnetic waves leaking from it. In this treatment, the coaxial-slot antenna is connected to a microwave generator and a power meter. The input power and the radiation time for the antenna are set to 30.8 W and 30 s, the tumor was heated up to 42–45 °C where cancer cells die.

*5) Post-Stent Implantation ISR Monitoring in the Esophagus:* Esophageal cancer is the eighth most common cancer worldwide and the sixth leading cause of cancer-related deaths. The other conditions that cause esophagus blockage include ulcers, radiation treatment, and abnormal openings between the esophagus and trachea. An esophageal stent treats all the conditions that block the esophagus.

A wireless, battery-free, movable PDT (Photodynamic therapy) unit for esophageal stents to treat esophageal cancer is illustrated in Fig. 4, [82]. This device proposed a novel strategy using an electrochemical pneumatic soft actuator to move the PDT light sources in real-time close to the tumors, achieving exact and effective therapy for esophageal tumors. The flexible actuator adjusts to several bends, permitting it to spiral and cover a significant region inside the esophageal stent, expanding the range of PDT light. In-vitro cell experiments have shown the efficient destruction of tumour cells by PDT, with competent effectiveness observed at close distances to the tumour, thereby proving the feasibility of this device. A battery-free and flexible electronic esophageal stent for noninvasive wireless stimulation of the lower esophageal sphincter was proposed [90]. This stent comprises a flexible receiving antenna filled with liquid metal (eutectic gallium-indium), a superelastic nitinol stent, and a flexible pulse generator. Together, they allow 150% axial elongation and 50% radial compression for delivery through the narrow esophagus.

*6) Post-Stent Implantation and ISR Monitoring in an Aneurysm:* When an artery wall weakens or is blocked due to plaque build-up, the force of blood pumping can result in a bulge or aneurysm, as illustrated in Fig. 5(a). In aneurysm repair a tube-like stent is implanted to block blood flow in the aneurysm sac, as illustrated in Fig. 5(b) and (c). Aneurysm stents are made of a metal alloy (such as Nitinol, stainless steel, or Co-Cr) in a tubular form and covered with a fabric graft (typically polyester or PTFE). In some cases, when an aneurysm abnormally grows on either side of the artery, as shown in Fig. 5(b), coiling of the aneurysm sac is also required along with the stenting. While the stenting/coiling of aneurysms is an effective solution, continuous monitoring after stenting is needed to detect stent occlusion early. A smart stent for post-implantation monitoring of the aorta was discussed [91]. It contains several piezoelectric porous membranes positioned at numerous locations of a conventional covered stent, as shown in Fig. 5(d). These piezoelectric membranes function as ultrasonic power receivers and flow sensors. The position could be interior, exterior, proximal, mid, and distal. The piezoelectric membrane is a single ultrasonic receiver and a sensing element in vitro; it was experimentally verified. A stent-based antenna system was constructed for EVAR (endovascular aneurysm repair) applications [92]. Here, the stent is used as a receiver, which is placed in the body, and a wireless power transmitter is put externally. The stent antenna works at ISM (Industrial, Scientific, and Medical) 868, 915, and 2450 MHz frequency bands. A serpentine shape was chosen to realize the stent because it improves its stretchability. This system worked well in homogeneous and heterogeneous environments. The stent antenna shows multiband behaviour with peak antenna gains of −12.1, −11.7, and −22.4 dBi at the respective ISM bands and a WPTE of 4% at 10 cm and 1.6% at 15 cm Tx–Rx separation. In a research, stent system was used as an antenna to provide post-stent implantation biotelemetry [93]. The constituents of the stent antenna are multiple meshed rings assembled to form the stent. The stent antenna shows a wide impedance bandwidth (850–950 MHz), covering the two ISM 868 and 915 MHz frequency bands The proposed stent antenna has an omnidirectional radiation pattern with peak gain values of −20.8 dBi and −19.0 dBi at the 868 and 915 MHz bands, respectively. The authors also evaluated patient safety. Additionally, the optimum values of the link margin make it suitable for performing biotelemetry communications.

The wirelessly powered stent rectenna for EVAR was proposed [94]. It includes a novel in-body stent receiver antenna and an on-body wireless power flexible transmitter antenna. The stent is a receiver of nylon-coated metal wire, exhibiting mechanical stretchability and precise current distribution. In contrast, the flexible wearable antenna is used as a transmitter and easily integrates with the body. Endoleaks are direct blood

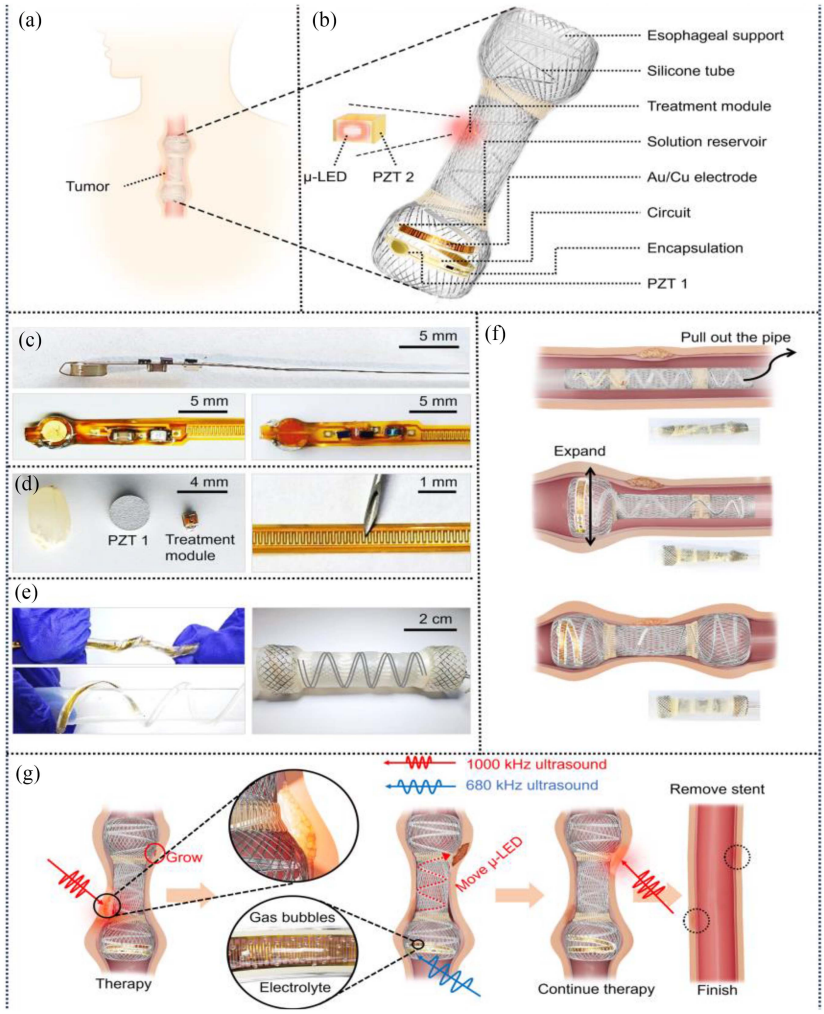



Fig. 4. Overview of the esophageal stent for tumor treatment. (a) The stent installed in the affected area. (b) The structure of the stent. (c) Photograph showing various configurations of the actuator. (d) The sizes of PZT 1 and the therapy module, smaller than a grain. The width and gap of the interdigitated electrodes are 80 $\mu$m, finer than a syringe needle. (e) The actuator can be twisted and bent, demonstrating its capability to integrate into the esophageal stent. (f) The process of implanting the stent into the cancerous area. (g) The treatment process of the esophageal cancer using the movable PDT stent system. [82].

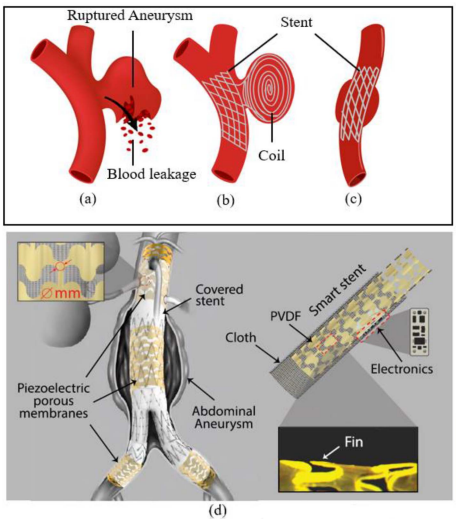



Fig. 5. (a) Aneurysm rupture, (b) Aneurysm stenting and coiling, (c) Aneurysm stenting, (d) Smart stent for blood-flow measurement in abdominal aneurysm [91].

flow into the aneurysm sac, possibly due to aneurysm expansion and rupture. One study mentions that post-stent implantation problems appear in 16% to 30% of cases and require secondary intervention [95], [96]. In another research, a smart stent was created by 3D printing and piezoelectric PVDF-TrFE filaments [97]. This smart stent can wirelessly sense and detect aneurysm pressure changes, helping in the early detection of post-EVAR complications. Furthermore, it can extract energy from blood flow in the human body and energize electronics onboard.

## IV. Safety Considerations of Smart Stents

In the previous section, we discussed different sensing mechanisms to detect ISR, wireless powering techniques to smart stents and ISR treatments offered by smart stents. In this section we have highlighted some important smart stent design considerations for patient's safety.

*Biocompatibility:* The development of smart stents requires coating to achieve biocompatibility. Bioactive coatings are composed of proteins and other biobased components to enhance

biocompatibility and functionality by promoting direct interactions and integration with living cells [98]. These coatings can be developed from natural biomaterials such as collagen, synthetic polymers like polyurethane, inorganic compounds like titanium oxide, or combination of natural and synthetic materials to improve bio functionality and mechanical behavior. These coatings can modify the surface properties of stents in many ways by influencing biological responses such as endothelialization, inflammation, and immune cell behavior.

*Stent heating:* In the previous section, we discussed hyperthermia treatment to cure ISR. Inductive heating of the stent to shrink the ISR was proposed [77]. The temperature range for this procedure was maintained at 45–65 °C. During therapy we need to take care of temperature because heating of stents more than 80 °C can cause thrombosis [74].

*Long term stability* depends on material choice, design and many other factors, such as loading conditions (due to initial deployment of stent and post implantation due to cardiac cycles), surgical procedure, and anatomy of artery or vessel. The positioning of biosensor and other electronics also play a crucial role in stable functioning of stent. The final coating of biocompatible material is also an important factor in successful sensing of ISR and long term stable functioning of stent [92].

*SAR* is an important parameter for smart stents and depends on multiple factors such as material, design parameters, and operating power of the stent. The maximum whole-body-averaged SAR is typically 2 W/kg. High SAR values are caused by conductive materials, such as stainless steel and cobalt-chromium alloys because these materials interact with the radiofrequency field and induce currents that cause hotspots of electromagnetic energy and heat up biological tissues [74], [99]. The length of the stent also plays an important role, if stent's length increases, then SAR value also increases [100].

## V. Limitations of the Smart Stents

Section III presented numerous types of pressure sensors, and their mechanisms used in post-implantation restenosis detection in different cases [101]. Still, there are open challenges in integrating different pressure sensors into the stents:

A PDMS layer is used to join the sensor to the stent. Even though it is widely used for microfluidic applications, it has low surface energy [102]. Consequently, it is not practical to use PDMS as a bonding agent because the stent is constantly subjected to the high pressure of blood. Additionally, as reported in [103], PDMS in contact with blood can introduce coagulation and thrombosis. In a study [104], compared to previous silicon-based sensors, 316l SS sensors offer the advantage of providing a reliable mechanical joint through laser micro-welding. Additionally, the sensors' platforms were gold-electroplated, and the entire smart stent system was coated with Parylene. Although this work provided a smoother stent system and reduced invasiveness, it has minimized sensing resolution and electrical failures during animal studies. In [64], the entire stent was utilised as an antenna to facilitate biotelemetry, enabling the transmission of blood pressure-related data to an external device. This work has two limitations: it does not consider biocompatibility, and the specific absorption rate was not assessed to ensure patient safety during telemetry and sensing.

## VI. Clinical Translational Barriers of Smart Stents

*Miniaturization and integration:* A smart stent would require a wireless sensor, associated readout electronics and communication infrastructure. To miniaturize the overall sensor dimension and integrate it with the stent, it is necessary to fabricate the sensor on the same substrate with the electronics. Several 3D printing techniques are available to print IMD sensors such as Fused deposition modelling (FDM) and high-resolution Stereolithography (SLA) but offer poor mechanical properties and are time consuming [105]. To realize a smart stent, fabrication and integration of all the components into one device is still a major challenge and needs more technological advancements.

*Wireless power transfer efficiency:* Wireless inductive power transfer efficiency to smart stents is limited due to coils misalignment, distance, and materials for near field inductive wireless power transfer [106]. Next, ultrasound energy transfer for stents faces signal attenuation due to reflection, absorption, and scattering of ultrasound waves, that reduces energy efficiency and causes beam distortion, and inaccurate power transfer [107]. Far-field wireless powering of stent was used in [60], [61], [18], [62], [92], [94]. It has low power efficiency compared to near-field methods, and we need to explore some novel antennas and methods to improve efficiency.

*Regulatory approval and safety standards:* Bringing smart stents from bench to marketplace will need a regulatory framework. There are several crucial standards be met for smart stents such as implement a quality assurance conformity assignment on design, fabrication, specification (ISO13485), useability (IEC62366), biocompatibility (ISO10933), electrical safety (ISO60601), sterilization (ISO11737), medical software and data protection (ISO62034) as well as labelling, packaging (ISO15738) with of course reference to good manufacturing practice (GMP) of the final device [105].

To ensure patient's safety, we analyze SAR (as previously discussed in part B, Section III) but over 6 GHz, power density (PD) is the accurate measure of safety because wavelengths are too small ($< 1$ mm) to penetrate biological tissue and they remain only on the surface [108]. FCC and ICNIRP PD restrictions are same for the mm Wave bands. For far-field exposures, where the electric field is uniformly distributed over the human body, the PD should not exceed 1 mW/cm$^2$ for the uncontrolled exposure and 5 mW/cm$^2$ for the controlled exposure. However, there are no FCC and ICNIRP guidelines for near field mmWave frequency exposure for dosimetric quantities [108].

## VII. Future Scope

In this section, we outline possible ways to improve the smart stent technology.

### A. Smart Stents for Robust Sensing and Monitoring of ISR and Timely Treatment

There are extensive scientific studies on smart stents, with the majority focusing on pressure sensors. However, there are

limited studies on employing other sensing mechanisms, such as ultrasonic sensing [54] and bioimpedance sensing [56], [57]. The ultrasonic sensors struggle to detect late ISR [109]. The bioimpedance sensor may be sensitive to its positioning within the stent. If positioned near the artery or vessel wall, it could identify clinically harmless cell growth related to healing after the stent implantation [110]. Also, the frequency of usage of the bioimpedance sensor and the level of the current applied by the electrode to the vessel wall needs to be investigated further to ensure its not affecting the heart's natural electrical system [110].

### *B. Improved Wireless Data Telemetry and Wireless Powering Techniques*

Near-field and far-field wireless power transfer (WPT) systems can be improved by enhancing efficiency, safety, and biocompatibility. Inductive WPT can be improved by optimizing the design of coils, using best-quality materials, and minimizing the losses [111]. In a study, a novel method of multi-coil systems to improve WPT efficiency was developed [112]. Advanced antenna design for far-field wireless powering of stents is crucial to improve the far-field WPT efficiency for stents. Wireless intrinsic power transfer methods can also be explored, in which energy can be motion, muscle contraction, respiration, heartbeat [113]. We can also explore energy harvesting methods that extract chemical, kinetic, and thermal energy from the body [114]. Smart stents can use the body's inherent mechanical energy from arterial pulsations and blood flow to power the device. This is often achieved through technologies like triboelectric nanogenerators (TENGs), which convert mechanical movement into electrical energy, and avoid the need for external power sources or batteries [115].

### *C. Using mmWave, THz, and Optical Frequencies for Antenna Miniaturization*

To further reduce the antenna used in RF wireless power transfer, mmWave, THz, and optical frequency bands can be considered, since radiation in these frequency bands is non-ionizing and considered safe as per FCC and ICNIRP standards. In a recent study, a thermal safety analysis was performed on skin at various frequencies such as at 130 GHz, 1 THz, and optical frequency of 1030 nm wavelength [116]. But experimental verification was done on bacon (a non-living tissue) at 130 GHz frequency, bandwidth of 10GHz, with maximum power of 20 mW and noticed a gradual increase in temperature by 0.8 and $1^{\circ}$C after 2 minutes exposure in different parts of the bacon. Despite positive results, we need FCC/ICNIRP standards for IMDs in these frequency bands and more research to get the actual impact of these frequencies on biological tissues [116].

### *D. Non-Invasive Emerging Volumetric Sensing Technique*

A non-invasive free-space tissue sensing up to 100 GHz is an emerging volumetric sensing technique. In a study, results underline a reasonably attenuation, a high muscle RCS (Radar Cross Section), and the attainable dynamic range needed to reach the muscle surface, thus giving information of its deformation throughout movement [117]. In future, such techniques can be used in ISR sensing.

### *E. Deep Learning Methods for Early Bile Duct Obstruction Due to Cancer Development*

Deep learning methods to detect cancerous blockages in early stages can be helpful. In recent research, a deep neural network method for tumor margin identification in electromagnetic imaging is proposed to distinguish the border between the normal and tumor parts to optimize the tumor removal surgery [118]. This capability can also be helpful in identifying cancerous blockages inside the bile duct and can help in deciding more optimized treatment plan in severe cases.

### *F. Improved Stent-Based Healing Techniques*

Some stent-based potential methods to treat ISR are discussed here.

*Hyperthermia:* Many research groups have proposed hyperthermia as an effective treatment for ISR. A MEMS-based capacitor attached to the stent works as a resonant circuit and produces heating at its resonant frequency helps to remove ISR [70], [71].

*Vibrating piezo plates*: A stent with the integrated vibrating piezo plates to stop the deposition of low-density lipoproteins (LDL) floating in the blood was proposed to overcome the occurrence of ISR [72].

*Resonant heating-based revascularization:* A novel ISR treatment, when the blood pressure sensor detects ISR development, a high power of approximately 30 W is applied for 320 seconds to expand the nitinol stent (designed to expand in more than one diameter) [76].

*Light therapy (PDT):* In the oesophagal stent, PDT was proposed [82]. In this therapy, a light-sensitive drug is given to the patient, which is activated by the PDT source by moving it to the affected location to kill cancer cells.

*Inductive WPT for stent heating:* The stent that can be heated up using inductive WPT to shrink the ISR as proposed [77]. The temperature range of the stent in this procedure was maintained at 45–65 °C.

*Gene eluting stents* use the stent structure as scaffolds to distribute local gene transfer to the vascular system where the stent is implanted [5]. This method permits persistent drug-elution and can block a multisystem immune response. The stent must be coated with biocompatible anti-inflammatory and anti-thrombogenic layers [119].

*4D printed stent:* 4D printing is a technology that introduces a time-based factor such as temperature, electric fields, biological signals, or light as a [120] to traditionally static 3D-printed constructs, thus supporting the construction of dynamic structures that respond to external time-dependent stimuli. The foundation of 4D printing is the sensible choice of stimuli-responsive biocompatible materials, such as hydrogels, shape memory, and liquid crystal polymers [121]. The 4D printing utilizing the shape memory effect, researchers at ETH Zurich have used it to construct vascular stents approximately 40 times more compact

in diameter than commercial stents [5]. In an article, the authors utilized shape memory effect with 4D printed thermo-responsive stent BRS with a very small diameter of 5 mm [122]. It will be less invasive during implantation into the coronary artery, where after reaching its desired location, it receives heat and can attain the diameter of the coronary artery. In the future these types of miniature stents may provide suitably small stents to be used to treat critical limb ischemia. Still, the long-term biocompatibility of stimuli materials is important to study as it might be affected by their stability, degradation rate, and potential for immune response [123].

*THz frequency-based demethylation treatments:* A system generating THz waves at the 10-mW level was developed to study the demethylation behavior of cancer DNAs by strong THz-field irradiation near the molecular resonant frequency of 1.6 THz [124]. There was significant reduction in the methylation levels of cancer DNA by 19% after 30 min exposure, compared to untreated samples. This approach is very low-power high frequency as compared to the conventional ablation methods [68] and can be explored to treat the bile duct cancer blockages.

## VIII. Conclusion

This article reviewed the developments in biomedical stent and smart stent technology from various perspectives, including materials, design, expanding mechanisms, and applications for different diseases. As an emerging technology, we focused on wireless smart stents and their effectiveness in sensing and monitoring ISR by integrating various sensors, antennas, and wireless interfaces into the conventional stents. The simultaneous functioning of smart stents as therapy devices to cure ISR is also discussed, along with in vitro and in vivo results demonstrating promising efficacy. We also compared the limitations of different stents, and finally, in the future scope section, we discussed techniques to improve wireless sensing and monitoring, along with the latest healing techniques, such as gene-eluting stents, 4D printing technology, and THz frequency-based demethylation treatments.

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