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INTRAVASCULAR IMAGING (A. G. TRUESDELL, SECTION EDITOR)

A Brief History of Intracoronary Imaging

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Abstract

Purpose of Review The purpose of this paper is to review the history of intracoronary imaging as it pertains to the development of intravascular ultrasound (IVUS) and optical coherence tomography (OCT) devices.

Recent Findings Coronary angiography continues to maintain its stronghold as the diagnostic modality of choice in the diagnosis of coronary artery disease. Limitations in scope, however, have necessitated the development of adjunctive forms of imaging through IVUS and OCT in order to augment the comprehensive assessment and therapeutic management of angiographic findings.

Summary IVUS and OCT have significantly enhanced current day percutaneous coronary intervention. Over the last 30 years, advancements in their design and technology have solidified a framework for clinical decision-making in the cardiac catheterization lab and have helped more accurately assess and treat coronary artery disease.

Keywords Intracoronary imaging · Intravascular ultrasound (IVUS) · Optical coherence tomography (OCT) · Coronary angiogram · Coronary artery disease · Interventional cardiology

Introduction

Since the first successful balloon angioplasty was performed in 1977, the field of coronary angiography and intervention burgeoned with numerous advancements, including drug-eluting stent (DES) therapy and unique strategies to treat complex coronary lesions [1]. Despite this surge and widespread clinical applications, coronary angiography had several limitations that prevented a more in-depth assessment of individual atherosclerotic plaques.

Intravascular ultrasound (IVUS) was introduced to enhance lesion characterization and visualization and aid in clinical decision-making during percutaneous coronary intervention (PCI). An IVUS image was a gray-scale ultrasound image produced by a small ultrasound transducer mounted on the tip of an intracoronary catheter that analyzed sound waves reflected from the coronary artery wall [2]. These reflected waves generated a cross-sectional, 360-degree view of the vessel. With the addition of IVUS, characteristics of a plaque, vessel layer details, and deeper tissue characterization could be added to the luminal profile of the coronary angiogram (Fig. 1).

IVUS had its own limitations as well, as its relatively low resolution limited what could be characterized within

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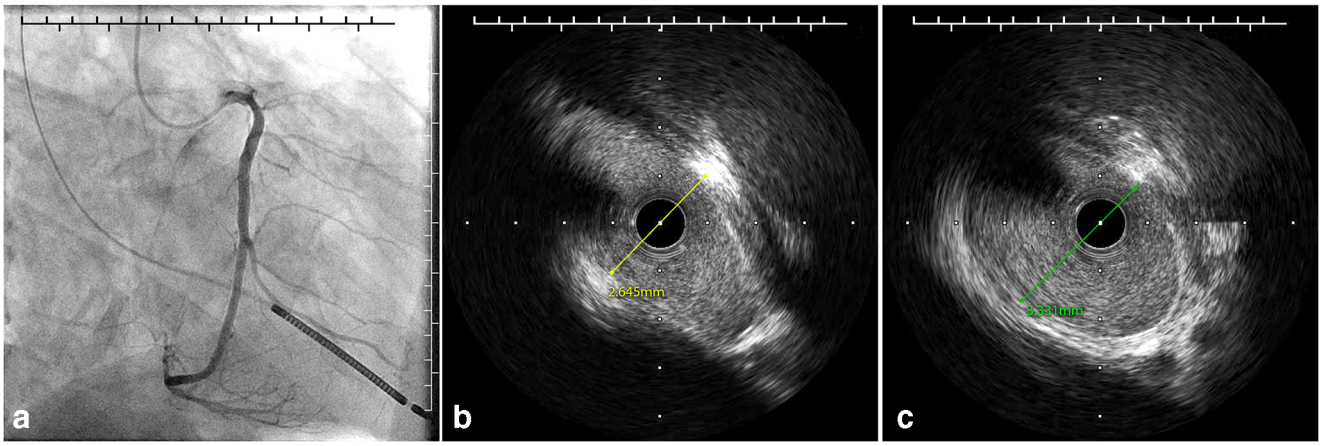

Fig. 1 A patient with anomalous right coronary artery with ostium from the left coronary cusp (**a**). Dynamic imaging with intravascular ultrasound demonstrates systolic compression (**b**) and diastolic decompression (**c**)

atherosclerotic plaques. Optical coherence tomography (OCT), a light-based modification of the IVUS concept, provided further refinement to the analysis of coronary lesion surfaces. Although lacking in the depth of penetration that IVUS provided, OCT offered almost a tenfold higher degree of resolution and thus aided in the assessment of stent placement parameters such as stent wall apposition, edge dissection, and strut coverage [2, 3].

Together, IVUS and OCT have revolutionized PCI and allowed for more refined plaque/lesion characterization, stent placement/optimization, and assessment of PCI complications. Both technologies have advanced over the past 30 years from being a research tool to a proven therapy that improves clinical outcomes among patient undergoing PCI [4–6]. Here, we review the history of intracoronary imaging with a particular focus on the origins of IVUS and OCT and their early evolution over the last 30 years (Fig. 2).

Benefits of Lesion and Device Imaging

Coronary angiography provided a two-dimensional outline of an atherosclerotic plaque based primarily on visual estimation. Reliably characterizing this silhouette, however, was challenging and unfortunately associated with a high rate of inter- and intra-observer variability even among the most skilled of operators [7, 8]. Poor correlation with post-mortem examination of coronary vasculature was also noted, further suggesting that visual inspection during angiography was limited [9]. As expected, angiographic lesions with near-complete stenoses and those with minimal to no obstruction were more likely to be reliably assessed. However, both under- and overestimation of more indeterminate severity lesions occurred commonly [10].

Coronary angiography was also limited in its ability to assess plaque composition, including the presence and degree of calcification and the presence of thrombus [2]. Such characteristics proved useful for prognosis and therapeutic considerations. Geometric features of a lesion including the severity of stenosis, actual vessel size, relationship to branch vessel, and length were difficult to define on angiography alone and were addressed by intracoronary imaging. Finally, due to the eccentricity of coronary lesions, some appeared normal on angiography but contained clinically significant atherosclerotic disease [11, 12]. As stenting became the mainstay of PCI, stent optimization became a central focus for clinicians. Imaging technologies aided in optimal stent placement, leading to less stent thrombosis and in-stent restenosis [13]. These technologies also helped minimize stent under-expansion and enhanced strut apposition against the arterial surface.

Intravascular Ultrasound (IVUS)

Early Cardiac Devices (Extravascular)

The concept of a probe-mounted ultrasound device dated as far back as the early 1960s when Polish physician, Tomasz Cieszynski, mounted a rudimentary ultrasound transducer on a small catheter to visualize the chambers of a canine heart in Wrocław, Poland [14]. Almost 10 years later, Bom et al. developed a more sophisticated phased array catheter by mounting a 32-element ultrasound transducer onto a 3-mm (9 Fr) catheter to evaluate human heart chambers and other intracardiac structures [15]. At this point, devices had not yet been designed specifically to evaluate human intracoronary anatomy and had been limited to internally assessing only the heart chambers themselves.

Some of the first depictions of human intracoronary anatomy via ultrasound occurred later in the early 1980s at the University of Arizona by Sahn et al., who used a 9- and 12-MHz surface ultrasound probe to scan epicardial coronary arteries in patients immediately prior to coronary artery bypass

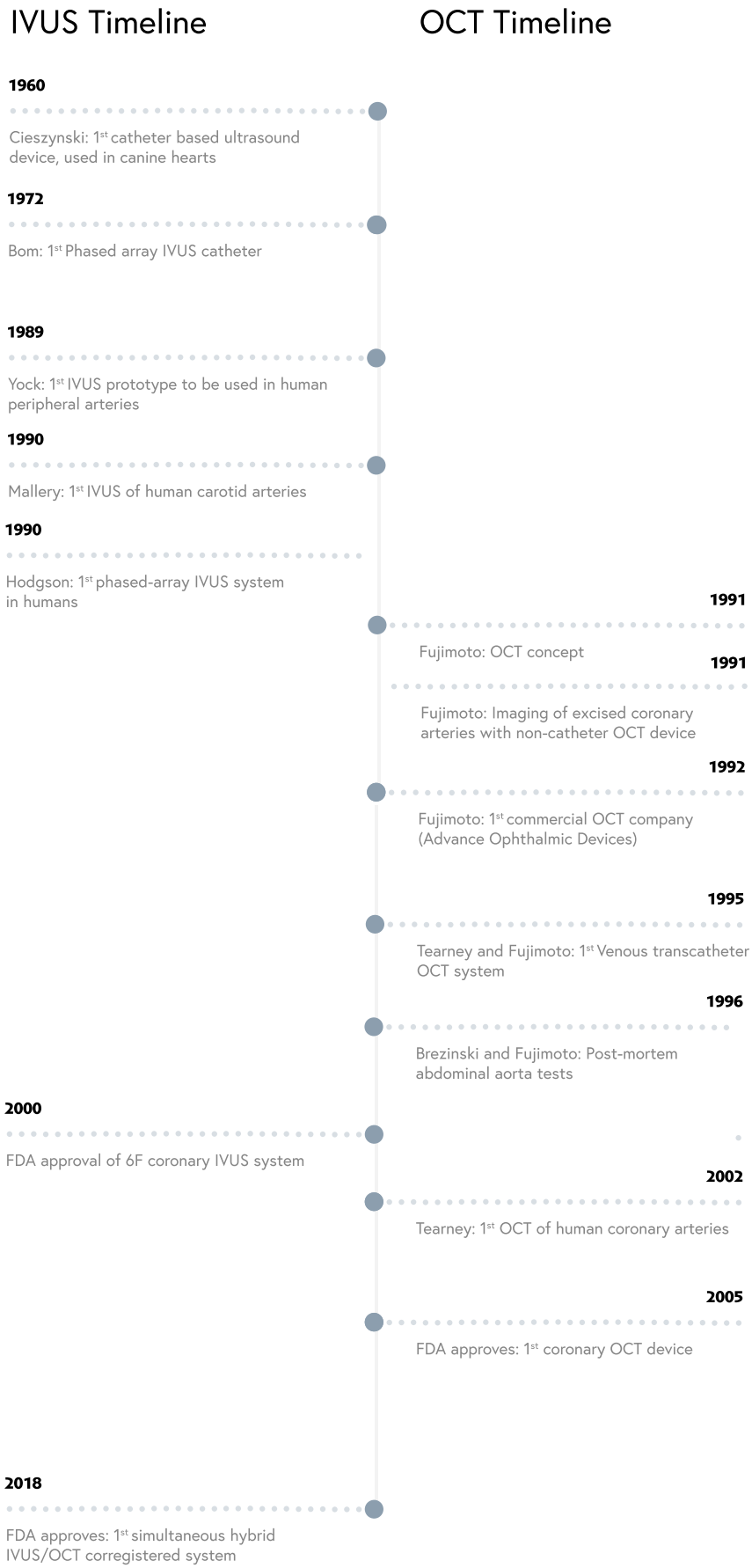

Fig. 2 History of key events in the development of IVUS and OCT

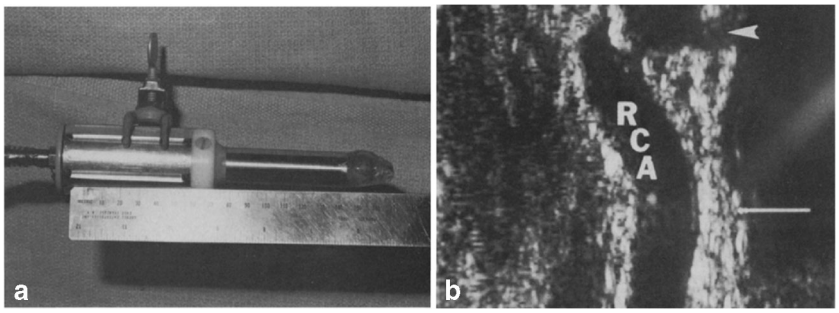

Fig. 3 Early images from intraoperative high-frequency epicardial coronary artery ultrasound [19]. **a** 12 MHz epicardial surface ultrasound probe. **b** Epicardial ultrasound image demonstrating atherosclerotic material within the right coronary artery with lesion shadowing noted by uppermost right arrow

grafting [16]. Through this modality, known as high-frequency epicardial echocardiography, the transducer itself was placed carefully on a beating heart prior to the patient being placed on cardiopulmonary bypass [16, 17]. Their efforts produced some of the first ultrasound images of coronary atherosclerotic lesions and helped introduce the concept of ultrasound shadowing, or the generation of dark ultrasound image "behind" or underlying a lesion due to the high reflective properties of the lesion itself (Fig. 3) [18, 19].

First IVUS Prototypes and Systems

It was not until the late 1980s and early 1990s that *intravascular* ultrasound prototypes were developed and tested. Paul Yock, through the University of California San Francisco and Stanford University, formally developed and described one of the first non-commercial IVUS systems [20]. Widely regarded as the father of IVUS, his device provided some of the first in vivo images of generic arterial structure, commenting first on the three-layered appearance of muscular arteries and the early thickening of the tunica intima in atheroma formation. His IVUS system consisted of a 20-MHz transducer mounted on catheters 1.6 mm or 2.6 mm in diameter (5 or 8 Fr) (Fig. 4) [21, 22] The system was operated by mechanically rotating a catheter containing a single large piezoelectric crystal at 1800 rpm to produce a 360° transmural view of a vessel. Images were registered in real time with frame rates ranging from 15 to 30 frames/s and recorded with a videotape thereafter. He was also able to detect plaque resolution more accurately than by angiogram alone. In several cases, angiography following atherectomy showed complete resolution of a plaque but IVUS detected significant residual

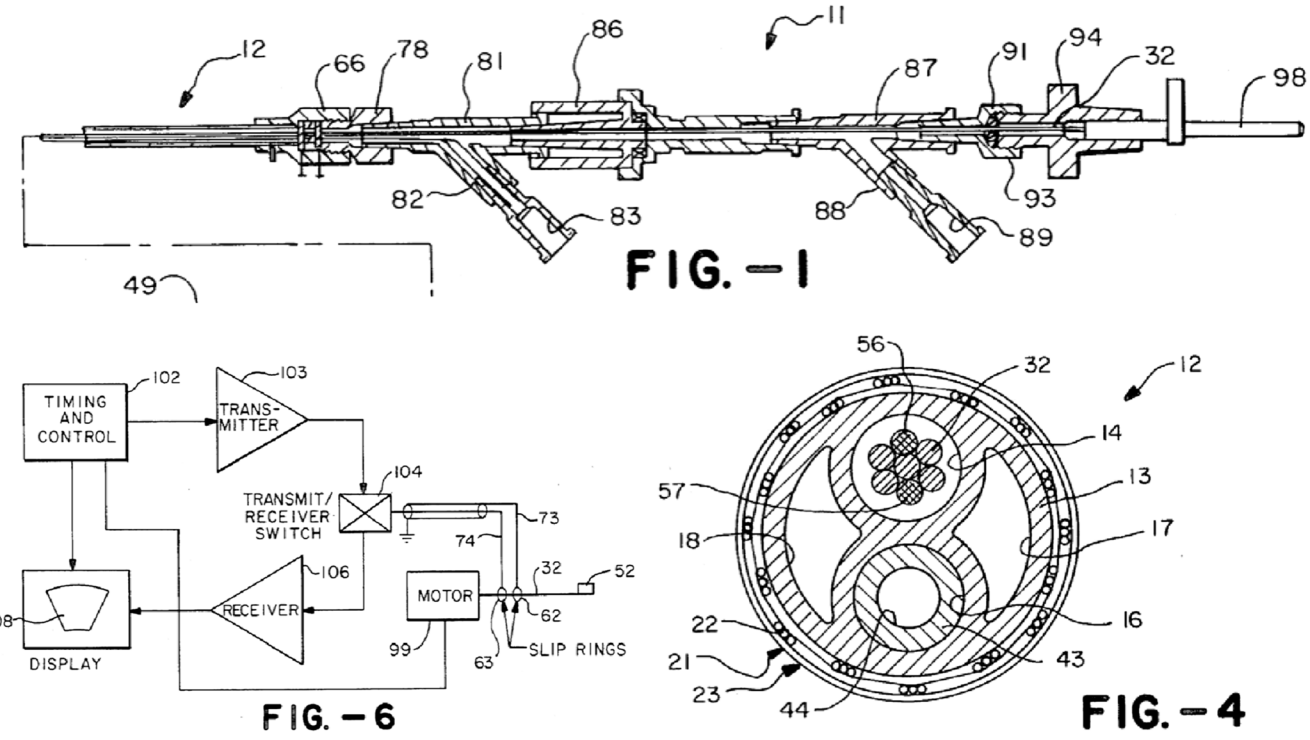

Fig. 4 Original diagrams of IVUS catheter design from Paul Yock's 1986 patent [22]. **FIG.-1** Side, partial cross-sectional view of the catheter apparatus. **FIG.-4** Axial cross-sectional view of catheter apparatus. **FIG.-6** Schematic block diagram of the electrical and electronic apparatus for the catheter system

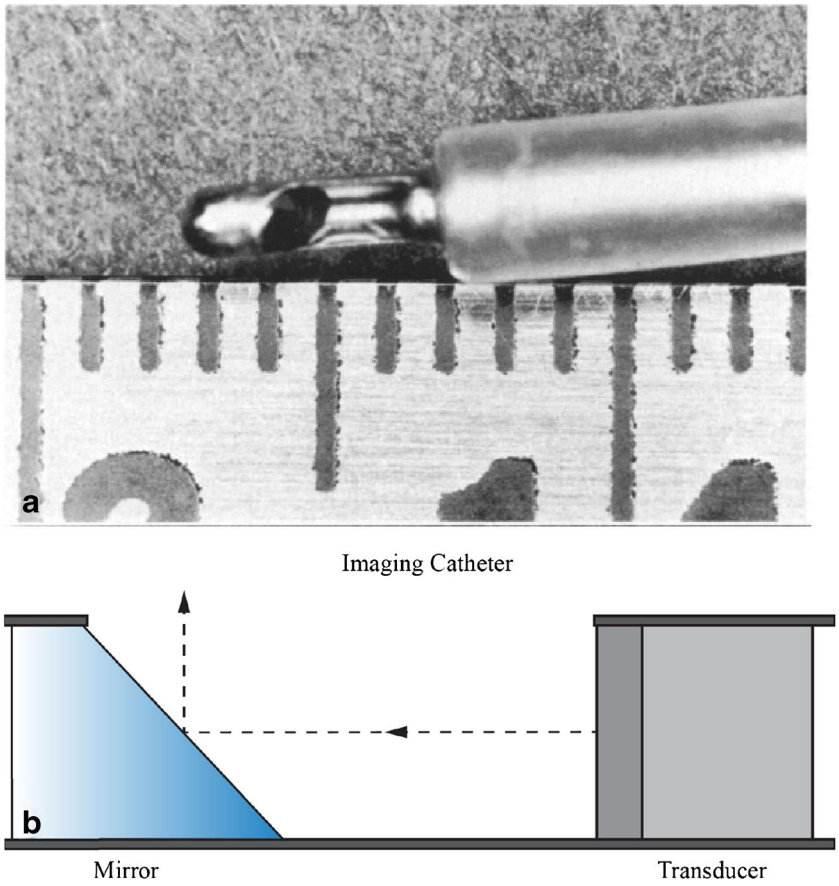

Fig. 5 Early IVUS prototype by Mallery and Tobis [25]. **a** Prototype ultrasound transducer with mirror at tip of catheter. **b** Path of sound travel in catheter tip

plaque burden [21]. During these initial studies, Yock also closely collaborated with a group from the Netherlands, who used a higher frequency 40-MHz catheter (DuMed, Rotterdam, The Netherlands) to analyze 112 excised human vascular specimens and correlate IVUS findings with those of subsequent histologic analysis. Plaque area, medial vessel wall thickness, and fibrous intimal thickening were all examples of lesion anatomy that correlated well between the two modalities [23].

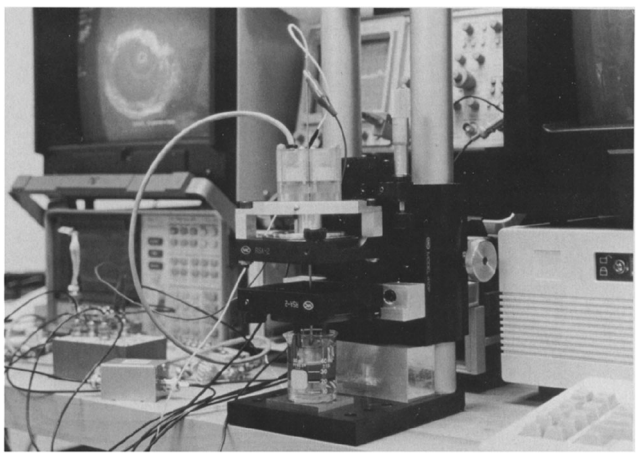

Fig. 6 Initial IVUS apparatus and setup used by Mallery and Tobis to produce initial IVUS images [25]. The distal end of the catheter system was passed through the sample arterial system in the beaker shown. The corresponding IVUS image was generated in real time on the monitor located in the upper left region of the image

In 1989, Tobis and Mallery developed a similar single 20-MHz catheter system (Intertherapy Inc., Costa Mesa, CA) that was tested on various coronary, iliac, femoral, and tibial systems in total at autopsy [24]. In comparison to Yock's system, their device employed a smaller 1.2 mm (3.6 F) diameter catheter that facilitated entry into smaller arterial systems. Their system also utilized mechanical rotation and generated an image through an ultrasound wave directed parallel to the length of the catheter that was reflected off a diagonal mirror to image the adjacent orthogonal artery surface (Figs. 5 and 6) [25] Through this, they were able to successfully quantify the distribution and quality of atherosclerosis in these vessels and also documented some of the first IVUS images of arterial systems prior to and after balloon dilatation angioplasty. Their work highlighted the necessity of a flexible, rotating catheter to be safely used in living patients.

Another group led by Hodgson et al. in the early 1990s finalized their results of one the first successfully tested "phased-array" IVUS trials in conscious patients. This phased array design consisted of several small transducer elements studded around the circumference of the catheter that were activated sequentially to generate an image [13]. Although

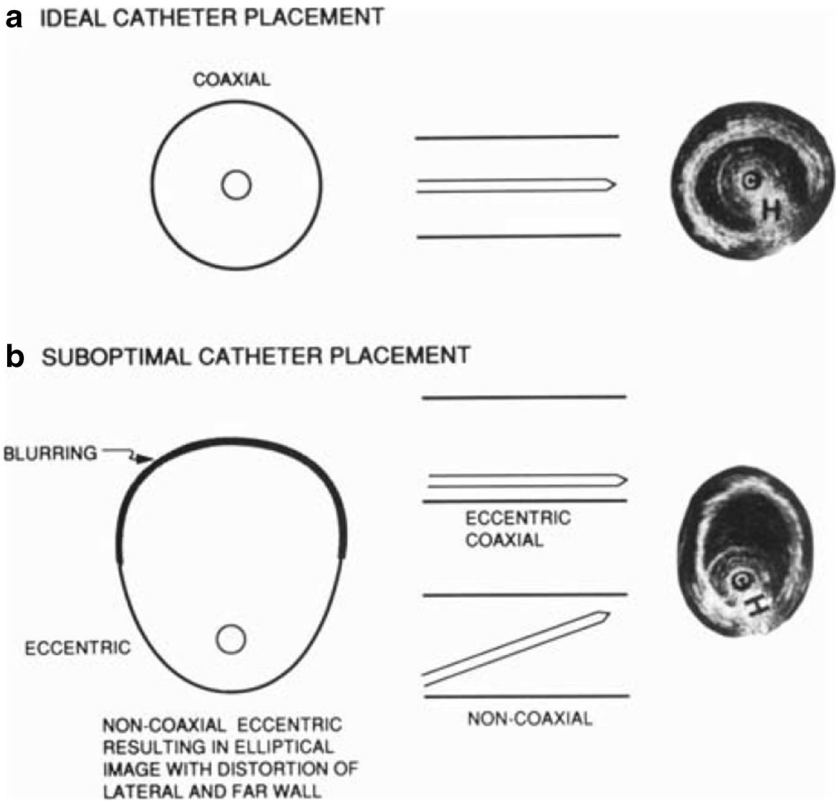

Fig. 7 Early limitations of IVUS systems included difficulties associated with ideal intracoronary catheter placement. Eccentrically located catheter tips necessitated re-positioning of the catheter to a more co-axial position to enhance image quality [28]

they similarly used 20-MHz frequency transducers (Endosonics, Rancho Cordova, CA), their catheter was slightly larger at 1.83 mm (5.5 Fr) and consisted of a synthetic aperture array that provided a simultaneous 360° field of view in contrast to a mechanically rotated side view [26]. This model was the first of its kind approved in the USA for intracoronary imaging and would serve as the primary counterpart to the mechanically rotated transducer for decades to come. In comparison to the rotating system, the phased array design offered the advantage of requiring a smaller access sheath to perform successfully. In addition, it was safer in tortuous arteries, as a mechanically rotating catheter generated friction against the arterial wall and hindered the generation of usable image [26]. Despite these benefits, controversy still remained initially regarding the superior system as some still professed that the mechanical systems generated higher resolution images. Hodgson's work was also one of the early examples of the benefits of using an "over-the-wire" catheter as opposed to monorail systems in which a guidewire ran adjacent to the IVUS catheter for much of its length [27]. The latter at that time were regarded as less safe due to the risk of mechanical vascular trauma [28].

Limitations of Early IVUS Systems

Despite the initial success and promise of early IVUS systems, there were several limitations that made imaging challenging. Perhaps the most salient of these was catheter size. In early systems, catheters that had been successfully tested in conscious patients ranged in size from 1.66 to 2.66 mm (5–8 Fr) [29]. This would ultimately limit access to only large vessels and those that lacked any degree of tortuosity. Early monorail systems required even larger catheter sizes [28]. Furthermore, the catheter tips that contained transducer elements were often inflexible over the length of their distal 5–8 mm, preventing further access to small arteries as well [29]. Eccentrically located catheter tips would result in significant distortion of the luminal and mural image, necessitating re-positioning of the catheter to a more co-axial position (Fig. 7) [28, 30]. Manual pullback in mechanical systems added an additional challenge to reliably acquiring an image.

Early phased array systems consisted of a limited number of transducer elements which led to suboptimal resolution [26]. This initially limited the presumed advantage over mechanically rotating systems. None of the designs thus far provided "forward looking" catheters that could successfully image lesions immediately distal to the catheter tip. Ring-down artifact occurred commonly. It appeared as a bright halo immediately surrounding the catheter that resulted from acoustic variations in the catheter tip [20, 31]. Ring-down artifact became a significant problem when the catheter was able to reach tighter spaces, as it affected structures immediately next to the imaging transducer [20]. Another prominent imaging artifact was non-uniform rotational distribution [32].

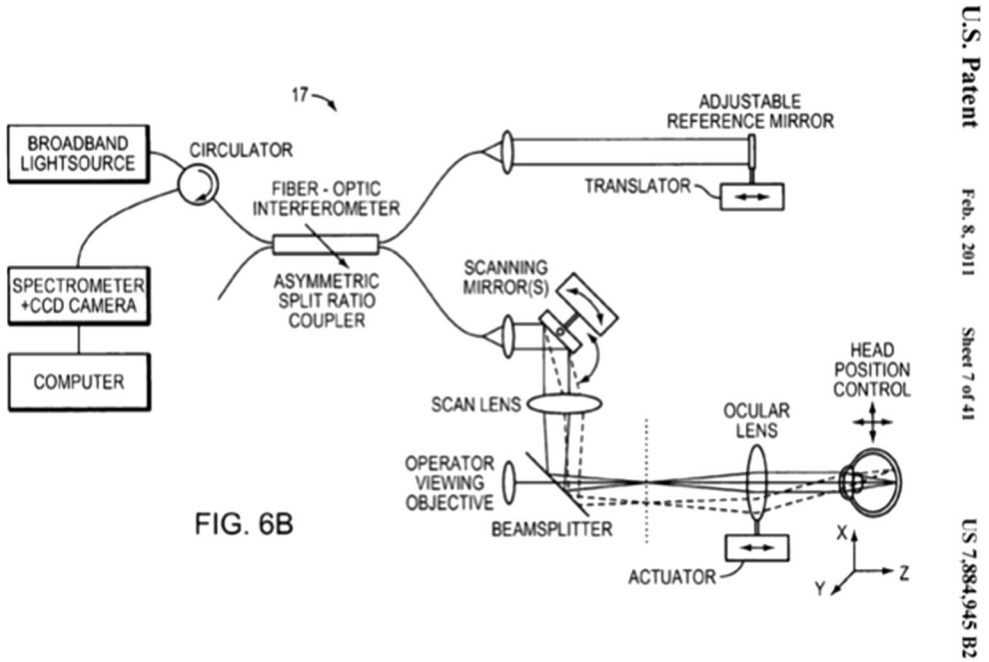

Fig. 8 Schematic from Fujimoto 2011 US Patent showing apparatus components of OCT system [44]

Mechanical IVUS catheters required uniform rotation to generate accurate images. If torque was unevenly distributed in the driveshaft, particularly in tortuous vessels, distorted images would result, ultimately causing errors in IVUS-derived measurements.

Newer Generation IVUS and Modern Systems

The newer generation IVUS systems that appeared in the late 1990s and through the early 2000s would strive to build on the limitations of past devices. Most notably, IVUS catheter sizes decreased to 0.87–1.17 mm (2.6–3.5 Fr) in diameter, permitting increased access to smaller vessels and those with tortuosity [9]. Higher frequency transducers were introduced during this time with ranges up to 40–60 MHz (Boston Scientific, Natick, MA) to further enhance lateral resolution [11, 20]. In order to measure lesion length reliably, automated pullback systems for catheter withdrawal were regularly used and operated at speeds between 0.25 and 1 mm/s [9]. Phased array systems incorporated an increased number of imaging elements arranged in an annular array to enhance image quality [33].

In 1998, Endosonics (Rancho Cordova, CA) produced the only Food and Drug Administration (FDA)–approved combined balloon-transducer system that permitted stent delivery with immediate IVUS imaging thereafter [34]. Yock et al. developed a prototype-combined IVUS-atherectomy device that could image regions that needed to be removed in real time [34]. Clinical interest in predicting "active" lesions or vulnerable plaques stimulated advancements in post-acquisition image analysis to provide information on plaque composition analysis. For example, virtual histology IVUS used spectral analysis and detection of subtle frequency shifts in Doppler data to color-code different components of atherosclerotic plaques [35]. Lesions through this modality could now be classified as necrotic core, fibrofatty, fibrous, or dense calcific [11, 36]. Thin-capped fibroatheromas, for example, appeared to be responsible for unanticipated cardiovascular events in a large prospective clinical trial [37].

Modern IVUS systems approved by the FDA in the early 2010s continued to add further refinements to older generations and were manufactured by companies including Medtronic, Philips Volcano, ACIST, InfraReDx, and Boston Scientific with capabilities far exceeding those of earlier systems. The Polaris imaging system (Boston Scientific), for example, was FDA-cleared in 2014 as a combined IVUS and fractional flow reserve (FFR) capable device that was intended to additionally assess coronary flow during IVUS. The TVC coronary imaging system (InfraReDx) in 2010 became the only FDA-approved system for the detection of lipid core plaques. The Philips Volcano systems added FFR, iFR (instant wave-Free ratio), and virtual histology within individual systems to further enhance the intracoronary imaging experience.

Optical Coherence Tomography (OCT)

Noteworthy Precursor Stages

Although OCT was newer in scope than its sound-based counterpart, it provided significant utility as an adjunctive tool in

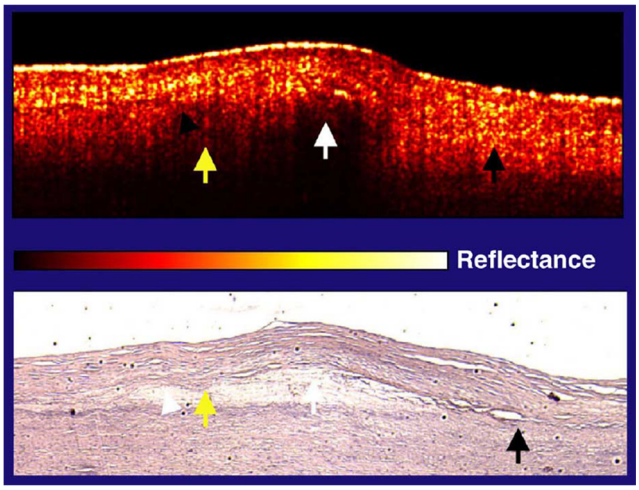

Fig. 9 Early 1996 OCT image of thin-cap lipid interface with histologic correlate below. The lipid-rich area is identified by the area of internal white in the lower image. The yellow arrow in the top image demonstrates an area of high scattering (yellow demarcations above) located above the lipid-rich rea. The white arrow points to an area of lower scattering, albeit still above the lipid area. The black arrow represents the normal intimal-elastic layer interface without the presence of underlying lipid [39]

intracoronary imaging and PCI. It was first introduced as a concept in 1991 by James Fujimoto, Eric Swanson, and David Huang at the Massachusetts Institute of Technology (MIT) and independently by Naohiro Tanno in Japan at a similar time [38, 39]. It was initially developed to enhance cross-sectional imaging of various body tissues by analyzing reflected near-infrared light and in particular, it was designed to further characterize the retina and optic disk of the human eye [40]. Given its high resolution and ability to finely discriminate between tissue planes, Fujimoto further applied this concept to the coronary vasculature, as it had similar complexities in boundaries between arterial wall layers.

Longitudinal and transverse scanning of the sample generated reflections of light from both the sample and reference

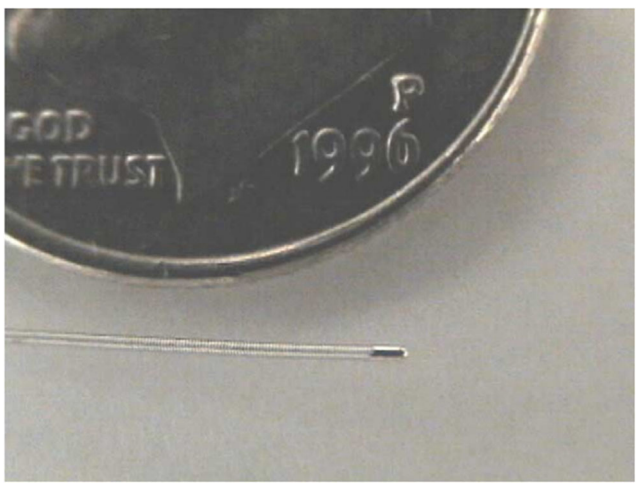

Fig. 10 Early OCT imaging catheter manufactured by LightLab imaging [39]

mirror that were compared and ultimately digitized to produce an image [40]. Through this, Fujimoto generated some of the first optical images of fatty-calcified and fibro-atheromatous plaques in dissected coronary artery specimens. With this initial success, Fujimoto along with Carmen Puliafito and Eric Swanson started the first commercial OCT company in 1992, Advanced Ophthalmic Devices, which would lay the foundation for future intracoronary applications of their technology [41].

First OCT Prototypes and Systems

One of the first OCT catheter prototypes was developed in 1995 through a collaborative effort by Brezinski et al. at Massachusetts General Hospital in association with Fujimoto and Tearney at MIT [39, 42]. Their 1.1-mm catheter-endoscope consisted of single-mode optic fiber that spanned the length of the device with a microprism and mirror located at the distal tip. As with the mechanically rotated IVUS device, this catheter too was rotated to scan the surrounding vessel in a circumferential pattern and could attain images at up to 30 frames/s with concomitant pullback along the vessel length.

In 1996, Fujimoto and Brezinski tested their prototype on segments of human abdominal aorta post-mortem and for the first time identified atherosclerotic, calcified, and thin-walled lipid-filled plaques using their catheter system [39, 43]. One of Fujimoto's first patent diagrams is shown in Fig. 8 [44]. Their primary caveat, however, was that their observations were performed chiefly using "in air" environment without blood present in the vessel wall. This would prove to be a significant limitation for initial models. In 2002, Tearney presented the first results of intracoronary OCT in living patients using a non-commercial 1.06-mm (3.2 Fr) modified IVUS catheter [34]. They compared their OCT images with those generated by IVUS systems of the same arteries and similarly commented on the significantly higher resolution that allowed for identification of fine details such as intimal hyperplasia, the boundaries between the internal and elastic lamina, thin fibrous caps, and other anatomical variations that could not be detected by IVUS (Fig. 9) [39].

LightLab Imaging (Westford, MA, USA) developed the first clinically available OCT imaging system (M2/M3 OCT system) and associated imaging catheter (ImageWire). An early imaging catheter is shown in Fig. 10 [39]. This first-generation system used a 0.41-mm fiber-optic wire in conjunction with an over-the-wire balloon occlusion and saline flushing system to provide a "bloodless" field to ensure adequate image quality. An automated pullback console retrieved the fiber-optic wire from the target system to generate images [45]. OCT analysis in this system was based on a time-domain modality in which tissue depth was determined by physically

modifying the distance to the reference mirror. This limited how quickly images could be generated [46, 47].

Limitations of Initial Models

The primary limitation of early OCT systems and in particular the M2/M3 system was the need for a "bloodless" field to image the arterial wall clearly [43]. The presence of red blood cells in the near field caused significant optical scattering resulting in a suboptimal image. Early models used an occlusion balloon that was placed proximal to the lesion and dilated at low pressure to reduce blood flow to the area of interest for up to 30 s [45, 47]. Another technique utilized repeated injections of 8–10 cc/s of saline that could at times clear an area up to 2 s at a time [46, 48]. Not only did this pose the risk of transient ischemia and inadvertent injury to the vessel at the site of balloon inflation; the process itself was laborious and proved challenging for severe stenoses. Only highly motivated operators were comfortable performing these procedures. Balloon occlusion would prevent assessment of ostial lesions or significant proximal disease of the left anterior descending or left circumflex arteries, as partially occluding an unprotected left main was highly discouraged [45].

Another limitation was that the relatively low frame rate of 4–15 frames/s and pullback speeds of 0.5–3 mm/s resulted in a fixed duration of time during which a segment of artery could be safely flushed for image acquisition [36, 46]. The low frame rate further had the potential to generate motion artifact as well [46, 48]. Lastly, although OCT provided impeccable resolution near the vessel surface, the depth of light penetration was limited, preventing further assessment of deeper plaque characteristics, such as the total lipid burden or changes in vessel remodeling [48].

Newer Generation OCT to Modern Systems

Newer OCT systems were developed in the late 1990s and early 2000s that addressed many of the structural and technical limitations of the first-generation systems. LightLab introduced the *frequency-domain* OCT system (C7-XR with Dragonfly imaging catheter) in response to the more cumbersome *time-domain* modality of the M2/M3 system. The frequency-domain system used a fixed mirror with a variable wavelength light source that measured data as a function of time and wavelength [46]. This significantly improved the ease of image retrieval and made OCT almost tenfold faster [49]. A 50-mm segment could now be successfully imaged in less than 3 s [45, 47]. These newer systems were also equipped with saline injection systems as fast as 4 cc/s, which almost entirely negated the need for sustained low-pressure balloon occlusion. The more viscous iodinated contrast became a preferential media for blood clearance, a factor that would need to be taken into consideration in patients with renal insufficiency. Tearney et al. were the first to test the frequency-domain system (Wellman Center for Photomedicine, Massachusetts General Hospital) in the coronary vasculature for the first time [50]. Their results demonstrated that all of the previous advantages of intracoronary OCT imaging could still be acquired with this faster, more efficient system.

Currently, OCT systems are approved for use by two major companies in the USA. LightLab, the official developer of the

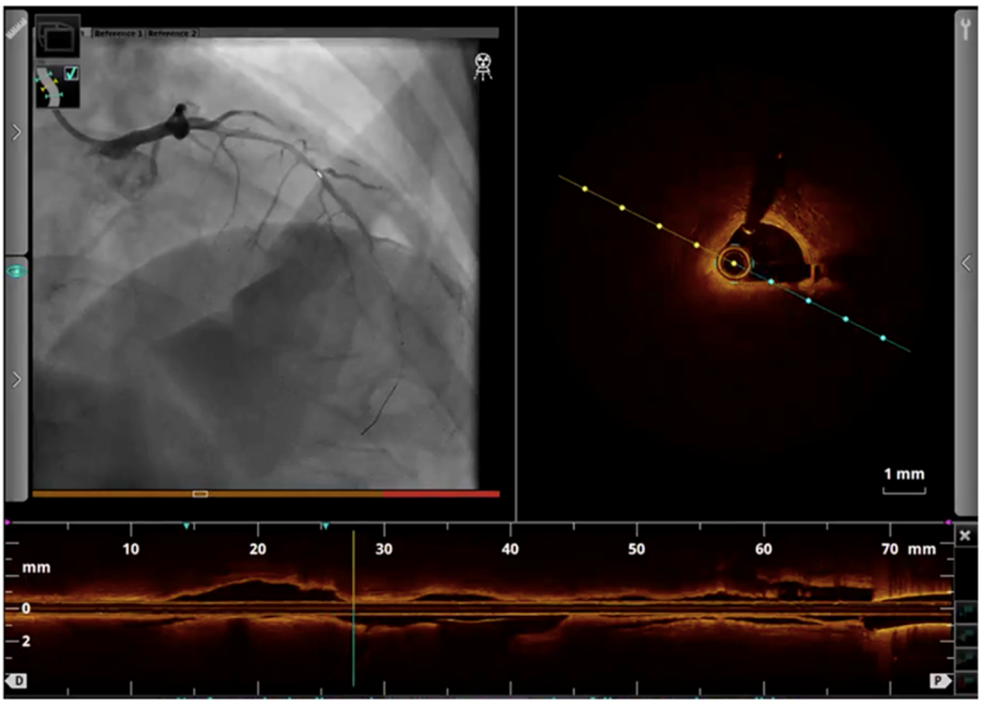

Fig. 11 Example of OCT co-registration. The white line indicates the position in the angiogram in the corresponding OCT image

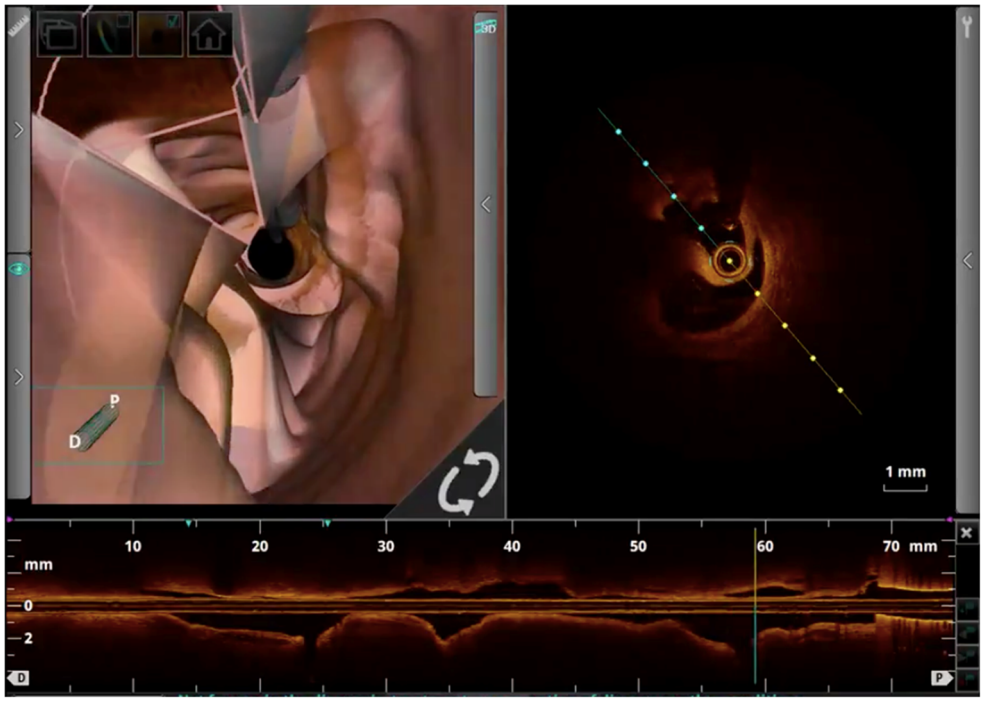

Fig. 12 Post-processing of an OCT image run showing 3D reconstruction of a coronary artery dissection

first system, was acquired by St. Jude Medical in 2014 and continues to produce the C7XR system in addition to the Ilumien Optis. The latter system is now able to simplify OCT image processing by helping guide stent diameter and length selection in real time [2]. Conavi Medical received FDA approval just recently in 2018 for its Novasight Hybrid System that combines IVUS and OCT into one catheter system. Terumo Corporation (Tokyo, Japan) is another company that is internationally renowned in cardiovascular device advancements and has developed OCT systems outside the USA [49]. Advancements in OCT technology include edge detection algorithms that automatically detect stent struts and their position within vessels [45]. Contrast-enhanced and molecular OCT is a sub-field dedicated to the use of microspheres, nanoparticles, and other dyes for the purpose of enhancing the transmission of light within tissues [51]. Automated tissue classification in real time is also a feature that is currently being developed, as it is currently a post-imaging process [2].

Modern Advances in Intracoronary Imaging and the Future

While advances and miniaturization of hardware continue to make improvements in resolution and accuracy of intracoronary imaging, innovations in how we use devices have continued to evolve. Exact correlation of an OCT or IVUS finding with an angiogram can be challenging. *Co-registration* of angiographic data to the IVUS and OCT images allows for the ability to align intravascular imaging data to the coronary angiogram (Fig. 11). Post-processing software has allowed us to visualize in 3D space lesions seen on images and has provided more detail in planning for complicated coronary interventions such as bifurcations (Fig. 12). The user interface has also greatly improved, with voice command and other hands-free technology allowing the operator to manipulate images without risking contamination. Finally, advances in augmented/extended reality technology may enhance the way we are able to visualize complex coronary lesions in real time.

Near-infrared spectroscopy (NIRS) represents a developing imaging modality that utilizes infrared light to characterize the lipid content of vulnerable plaques [52]. Its current utility is derived from its ability to identify high-risk lesions that may be prone to rupture and cause ensuant acute coronary syndromes [53]. Although first tested on arterial systems in 1993 by Cassis and Lodder, it is gaining increasing traction as a viable method to provide an instantaneous (< 1 s) chemical analysis or "chemogram" of arterial tissue [54]. Although not widely available, NIRS shows promise as hybrid IVUS-NIRS and OCT-NIRS catheters are being developed and tested to further augment intracoronary imaging [55, 56].

Conclusions

For much of the last 30 years, IVUS and OCT have defined the field of intracoronary imaging. Although their original applications were tailored to other body systems, their

relevance to the coronary vasculature and PCI was quickly realized and valued. From their humble beginnings in Paul Yock's and James Fujimoto's research labs, respectively, their imaging modalities have improved the ability to understand vascular lesions, plan therapies, and assess outcomes. Operators are now able to visualize atherosclerotic lesions with exceptional resolution and detail, enhancing both the efficiency and quality of stent placement. Intracoronary imaging through IVUS and OCT in the field of interventional cardiology has undoubtedly improved our understanding of coronary artery disease and will continue to do so for the foreseeable future.

Compliance with Ethical Standards

Conflict of Interest The authors do not have any relevant disclosures or relationships to disclose with respect to this manuscript.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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