Optimized ultrasound imaging catheters for use in the vascular system

R.J. Crowley¹, P.L. von Behren², L.A. Couvillon Jr.¹, D.E. Mai² & J.E. Abele¹
¹ Boston Scientific Corporation, Watertown MA, USA; ² Diasonics Inc., Milpitas, CA, USA

Abstract

Clinical experience with 6 and 9 Fr ultrasound imaging catheters (UICs) reveals that several transducer and catheter tip varieties are needed for optimum imaging of diseased intravascular sites. Our UIC design has combined established catheter design and very high frequency ultrasound imaging technology to create a versatile, user configured system for intravascular ultrasound imaging. Optimum use requires proper strategic selection of transducer and catheter sizes, frequencies of operation, and interventional accessories.

Introduction

New techniques for angioplasty, increasingly prominent in scientific conferences, are currently the subject of much enthusiasm and investment. There has been an accompanying strong interest in imaging modalities and guidance systems which might provide better evaluation of lesion morphology and character than traditional angiography.

Very few of the ‘new’ angioplasty techniques, or the guidance systems, are genuinely new. There are many references to thermal angioplasty, currettage (atherectomy), stents, electrical ablation, and other currently fashionable topics, in literature more than twenty years old, and patents from the 19th century [1]. Intravascular ultrasound is no exception; Bom has written an excellent historical summary describing work in this area [2]. The tendency of medical innovations to have a very long gestation time was studied in the 1970s by Rushmer [3]. These innovations have a tendency to be periodically rediscovered.

Our work suggests that optimized intravascular ultrasound products must apply the lessons learned over many years about catheter design, ultrasonic imaging, and the needs of the interventionalist.

Motivation

Our own interests in intravascular ultrasound have accompanied our work in balloon angioplasty from its beginning in the early 1970s. Over this period the use of balloons expanded from early pioneers and ‘hobbyists’ to the clinical mainstream. The barriers to the expansion of angioplasty and related less-invasive techniques have been systematically beaten down over the years, through a collaboration among device innovators and visionary clinicians. To be sure, many of these barriers have been medico-political as well as technological. Technical advances have not guaranteed clinical utility.

A key technical barrier to wider use and improved clinical efficacy of angioplasty, and the fundamental motivation for intravascular ultrasound, is the relatively poor information about vascular disease provided by conventional angiography. Angiographic views are two-dimensional shadowgram projections of contrast-opacified vessels. These two-dimensional images often provide a deficient or misleading representation of the actual three-dimensional vasculature. Lesion morphology and percentage of stenosis are not well quantified. Detailed visualization of anatomy and loose material or flaps is difficult because overlying tissue reduces contrast. The known harmful effects of
ionizing radiation, and concerns about osmotic effects of radiographic dyes, restrict the imaging time available. Nevertheless, angiography is currently the diagnostic 'gold standard' for the interventionalist.

Direct optical vision of lesions has been a longstanding dream. It was attempted in the 19th century using various glass tubes [4]. In the 1950s, rigid endoscopes using relay lenses began to appear, and were successful in certain applications where their size and stiffness did not outweigh their benefits. The development of coherent bundles of flexible optical glass fibers in the 1960s and '70s led to the growth of medical endoscopy as a key medical specialty, especially in gastroenterology and pulmonary medicine. Our own work in fiber optic applications resulted in a variety of inexpensive catheter endoscopes known by the name VisicathTM*[5].

Optical endoscopes have continued to improve in flexibility and resolution, and to decrease in size, during the 1980s. However, in spite of research enthusiasm, their application in vascular imaging has been limited and problematic. Blood obscures the optical image, and an image from within the lumen of the endothelial surface, although useful, does not provide information about the internal structure and composition of the vessel wall.

External ultrasound can provide detailed, real time pictures of vascular anatomy, including plaque character and location. Doppler ultrasound studies provide information on blood flow. However, external ultrasound is limited by frequency dependent attenuation which restricts its highest useful frequencies to the 10 MHz range and a maximum depth of about 4 cm. The lateral resolution is consequently limited, especially in deeper structures. Another major shortcoming of external ultrasound is that of acoustic access; it is often difficult or impossible to reach a target vessel with ultrasound energy because of an inadequate acoustic path in the overlying tissue. Lack of acoustic access severely limits cardiac studies. Another constraint is vessel tortuosity which makes scanning extended vascular segments difficult because only a small part of the vessel may lie within the thin tomographic slice of the ultrasound scan. Finally, vessel motion due to cardiac pulsation can move the subject in and out of the scan plane.

Table 1 gives an overview of the advantages and disadvantages of angiography, optical endoscopy, and external and intraluminal ultrasound.

### Design evolution

As part of an experimental assessment of excimer laser angioplasty, we concluded that intraluminal ultrasound was more likely to provide suitable anti-perforation guidance than alternatives like emission spectroscopy. To establish feasibility, a 1 mm diameter, 20 MHz air-backed hand-rotated transducer was constructed*, and used with rudimentary imaging electronics to produce images of wire phantoms and tissue samples. These images were crude, but provoked a next step, the objective of which was grey-scale images from a catheter with practical flexibility. We obtained improved 1 mm transducers, mounted them on various shafts, and began a series of in vitro and animal experiments.

Around the time of these initial experiments, the combined excimer laser-ultrasound system was abandoned. Attention was directed to an intra-vascular ultrasound imaging system for diagnosis and intervention with the following overall performance specifications:

- The catheter construction should be modular. Optimum economics are provided by a multi-use transducer within a single-use sheath having a sonolucent ‘window’ region.
- Numerous catheter designs and accessories must be provided, based on the variety of standard diagnostic catheter shapes and functions which have evolved in interventional medicine, and will continue to evolve.
- The catheter should have acceptable flexibility, torque properties, and feel, and be constructed from approved catheter materials. Generally, it should have performance characteristics already familiar to interventionalists.
- A family of system sizes must be provided: a 6 Fr

* Boston Scientific Corp., Watertown, MA.

* Craig J. Hartey, Houston, TX: personal communication.