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Ultrasound guided therapeutic catheters: recent developments and clinical results

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Abstract

The increasing use of intravascular ultrasound technology by clinicians is providing detailed and immediate information about the results of interventions, and this is stimulating the development of new catheters that use ultrasound imaging to control therapy in real time. Cold and thermal balloon angioplasty, atherectomy, embolectomy, laser ablation and rotational recanalization are a few of the interesting capabilities now being added to ultrasound catheters. We report on the development and characteristics of some of these devices and attempt to assess their potential to precisely direct therapy.

Introduction

First-generation ultrasound imaging catheters (UICs) are entering a new phase where performance and reliability issues are largely settled and broader commercialization has started. It is estimated that at least 140 centers worldwide are using commercially available UICs from at least four different manufacturers as of January 1991 [1], and diagnostic intravascular ultrasound (US) is gaining a foothold in assessing the short-term results of vascular interventions such as balloon angioplasty [2, 3].

Intravascular ultrasound products have advanced sufficiently where usable systems of catheters and imaging electronics are readily available to the clinician, and the commercial manufacture of these systems and catheters is now routine. A variety of transducer frequencies, catheter sizes and configurations, a few with unique capabilities, offer more optimal imaging of different intraluminal conditions and calibers [4]. At least two potentially competing imaging methods, single crystal (mechanically scanned) and synthetic aperture (electronically scanned) are available. This modest proliferation with attendant improvements in the state of the art provides a technical base for experimenters to construct more complex hybrid imaging catheters that are the subject of this review.

Perhaps any presently used interventional therapy could benefit by better control, faster feedback and a greater understanding of the immediate effects of the intervention. Without becoming too complex and cumbersome, catheter-based therapies might be more easily used if a higher degree of precision was available. X-ray imaging still provides most of the control and feedback modern interventionalists need for a wide variety of tasks, and most medical imaging experience has been accumulated with this imaging modality. Yet some interventionalists are now beginning to consider intravascular US as a potential primary diagnostic imaging tool and alternative to contrast arteriography [5]. To some extent, ultrasound has already been established as the primary guidance for certain other forms of 'less invasive' diagnoses and treatment, particularly by urologists. Ultrasound guided prostatic biopsy devices are now prevalent in major ultrasound equipment manufacturer's lines, for instance.

Hybrid UIC concepts

The long-standing desire to put US on interventional modalities such as lasers has been delayed to some extent while more basic imaging technologies are refined, yet some clinical studies using combination ultrasound imaging and therapeutic catheters have started. Our work with mechanically-rotated UICs led us to consider several alternatives for merging new or existing interventional therapies:

Laser hybrids

In the past several years, several intravascular US devices carrying interventional therapy have been proposed in the patent literature and at scientific sessions. Perhaps no single area has attracted more attention as a potential hybrid as laser angioplasty. Webster's 'Catheter for removing arteriosclerotic plaque', describes a laser angioplasty catheter with forward-directed ultrasound sensors arranged around a distal optical fiber window [6]. A-mode (ranging) and spectrally derived tissue character information could be usefully monitored during laser firing. Although not designed for B-mode imaging, the proposed device would sense the proximity and radial location of an obstruction, allow analysis of the backscattered signal to perform tissue characterization, and direct laser energy at a specific site. To steer the ablative energy, it is suggested that the catheter can be advanced and then torqued to place the laser output at the lesion site. The patent was precedent setting and has received attention from commercial firms interested in developing US guided laser angioplasty systems since its issue.

Another US guided laser angioplasty system is described by Angelsen and Linker [7]. The problem of making the laser energy coincide with the ultrasound image is solved by firing the laser through an aperture in the center of the imaging transducer. In this system, it is envisioned that simultaneous imaging and firing control could be accomplished, and that a definite relationship between image plane and laser emission can be maintained during use.

A different kind of US guided laser angioplasty system is described by Martinelli, et al. A magnetically coupled catheter position sensing antenna relates coordinate data from the catheter tip with simultaneously obtained acoustic data. The catheter also houses an ablating fiber. They propose that the laser be fired radially and in close coincidence with the ultrasound scan plane. To obtain the image, the catheter is moved manually to assemble acoustic information which can be used to generate coordinates for the control of the laser [8, 9].

That group has more recently adapted elements of their ultrasound and laser catheter system for the treatment of prostate disease. Presumably, experience gained can be applied later for use in a scaled down system for arterial recanalization.

Our own initial work in laser angioplasty had been to develop a system of catheters that would prevent perforation of arteries by incorporating US guidance [4, 10, 11]. We had speculated that hybrid catheters with both ablating and imaging capabilities would have commercial importance, and were encouraged by feasibility experiments that showed us that certain vessel features and disease could be resolved with high frequency imaging technology [12].

To speed and simplify development, we chose to separate most laser and ultrasound activities for later hybridization. But to gather some basic information, we constructed a prototype photoacoustic ablation catheter (PAAC) for *in vitro* experiments. A flashlamp pumped dye laser operating at 510 nm was used for the experiments. The PAAC consisted of a 400 micron fused silica optical fiber attached to the outside of a 6.2 F UIC. (Fig. 1). The distal tip of the optical fiber was then aligned with the UIC scan plane.

A formalin fixed segment of atherosclerotic human iliac artery was submerged in a saline bath, and a target plaque was identified by ultrasound imaging. Laser ablation of the target plaque was attempted using laser pulses of 250 mJ with a pulse width of 2 μs and a repetition rate of 2 Hz. The laser pulses produced an audible popping sound, and bubble formation at the interface between fiber and plaque could be seen with US. This effect was cumulative. Since the artery segment was not perfused, the bubbles formed by the laser ablation process severely degraded the image quality, but this effect did diminish over time. Although we had speculated that acoustic noise generated by the laser would interfere with imaging, no acoustically derived artifacts were noted.

By adjusting the relative position of the PAAC and the vessel segment, we were able to ablate a portion of the plaque. Close coincidence of the image plane and the point of laser energy impact was evident by the appearance of small hyperechoic bursts seen close to the center of the image. Complete ablation of the target plaque could not be accomplished. Interference of the PAAC tip and remaining lesion prevented the side mounted fiber from effectively contacting and ablating remaining tissue.

Since this experiment was not performed in flowing blood, we could not determine if the image clutter created by the gas bubbles would normally clear rapidly to allow continuously monitored application of the laser energy. However, these observations tend to confirm the suspicions of Borst, et al.; it seems that if a photo-acoustic type laser system is used, perfusion will be required to clear the bubbles formed in the image field [13].

Spark erosion hybrids

Vaporization of plaque is one of the ablating mechanisms that lasers and spark erosion share. Like lasers, spark ablation generates a high temperature plasma discharge which erodes material and generates a gas by-product. Its operation is quite similar in principle to electrical discharge machining (EDM) techniques used to fabricate conductive components. EDM efficiency, and therefore the rate of erosion, is known to vary with the conductivity of the material to be removed and the magnitude of the applied current [14]. These principles could be applied to selectively remove plaque without injury to the vessel wall by sensing variations in tissue impedance. *In vitro* and *in vivo* studies using a radio-frequency powered spark erosion guidewire have shown that controlled vaporization of an atherosclerotic lesion is possible, but that perforation of the vessel wall is likely [15].

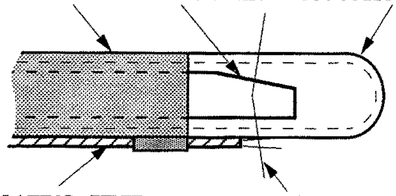

Fig. 1. Photo-acoustic catheter (PAAC) layout. Image plane intersects end of ablating fiber at side of acoustic window.

To solve this problem, Bom et al [16], suggested that recanalization of obstructed and eccentric lesions with spark electrodes could be successfully controlled by incorporating a single 20 MHz ultrasound transducer just behind the catheter tip. In Bom's ultrasound equipped version of the spark ablator, an arrangement of three or more independently fired electrodes are located at the catheter tip near the electrodes. As the transducer images, the radial position of obstructive lesion would be visualized. Energy would then be delivered to the specific electrode adjacent to that position. The result would be that effective steering of the therapeutic energy could take place in eccentric lesions, presumably reducing or eliminating the potential for perforation. Prototype US-guided spark ablators were built and tested by Bom [16].

Atherectomy hybrids

Directional atherectomy has recently been the subject of proposed US hybridization [17]. The side-cutting Simpson Peripheral AtheroCath TM (Devices for Vascular Intervention, Inc. Redwood City, CA, USA) uses a driveshaft powered cutter that traverses a window in a cylindrical shell. Under angiographic guidance, destructive material is pressed into the opening by the action of an opposing positioning balloon and is sliced off and collected in a retrieval chamber. Rotation of the cutter

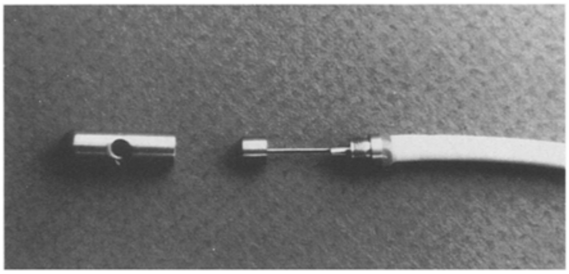

Fig. 2. Meditech suction biopsy device, ca. 1978. Left to right: Capsule with orifice, cup-shaped cutter with sharp rear edge, control wire, steerable catheter body. Negative pressure is used to pull tissue into orifice.

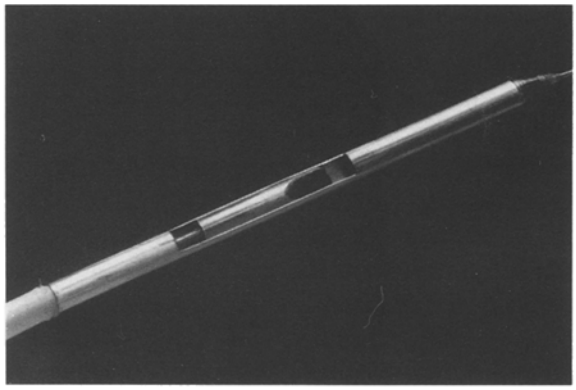

Fig. 3. Prototype US guided atherectomy catheter used for *in vitro* experiments. Transducer (dark ellipse) is seen at distal orifice. Cutting edge is on rear of transducer housing.

and special cutting edge geometry assist in severing tissue. Although the depth of cut is regulated by the amount of lesion that can be pushed into the cutter opening in a given position, optimum results might be obtained if the extent of lesion could be more precisely determined. To this end, Yock has proposed to incorporate a single element transducer on the cutter so that images can be obtained virtually simultaneous with the cutting action. This would allow the interventionalist to avoid weakening or perforating the vessel wall by removing the bulk of the lesion without damage to underlying tissue [18, 19].

Our own experience with the side cutting Suction Biopsy device (Meditech, Inc., Watertown, MA 02172), suggested that adaptation to ultrasound imaging would not be too complicated (Fig. 2). In place of the cup-shaped internal cutter, a 9F, 20 MHz Sonicath TM transducer was substituted. A 0.043″ driveshaft was welded to a 0.088″ transducer to provide stepped clearance around a cutting edge fashioned by sharpening the transducer housing rim. The outer biopsy housing was lengthened to 3 cm and the orifice was lengthened to allow a generous cutting area. A sliding fit between the transducer and the housing was provided to allow the transducer to rotate and slide within the housing, which was bonded to an 8F catheter body. A traverse handle was attached to the proximal end of the catheter near the motor connection. Acoustic coupling would occur when fluid entered the housing, and excised material would be collected in the proximal end of the housing where it meets the catheter body. Finally, a distal guidewire was added to simulate the appearance of a conventional side cutting atherectomy catheter (Fig. 3).

To test the prototype catheter, a 4 mm diameter lumen was bored in a tissue phantom which was immersed in water. Imaging started as soon as fluid contact with the exposed transducer was established, and the system motor energized at a speed of 600 RPM. The catheter was then directed manually into the lumen. Finer positioning of the device was accomplished from on-screen US images. The rotating transducer/cutter assembly was then advanced into the distal housing, which exposed the cutting surface. While this action interrupted imaging temporarily, light pressure was applied to initiate cutter contact with the tissue. Without changing the position of the catheter, the cutter/transducer was retracted across the orifice, simultaneously severing the adjacent tissue and restoring the US image. A distinct notch in the luminal circumference was then observed with US (Fig. 4).

The prototype device was able to provide *in vitro* imaging over an angle of approximately 90 degrees, though edge diffraction of the US beam compromised lateral resolution as the transducer rotated past the edges of the orifice. Reverberation artifacts were the result of strong internal reflections from the metal housing. An acoustically transparent housing has been proposed by Yock to solve these problems [18]. Some near field image clutter

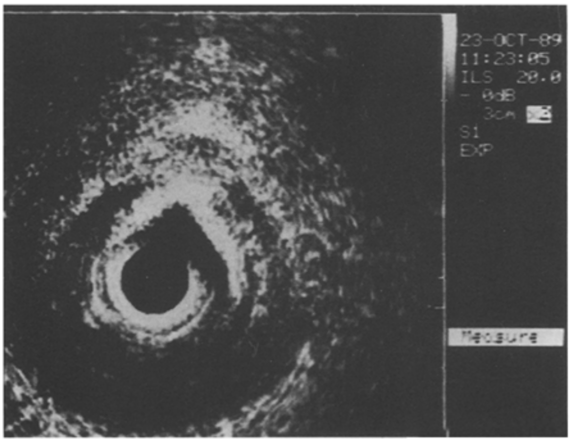

Fig. 4. In vitro post atherectomy image. Notch from cutter is at center. Bright crescents at lower left and above notch are reverberations from the metallic housing.

was evident when direct tissue to transducer contact was made.

Mechanically, the device appeared to be workable: it was possible to adjust clearances and manage friction so that smooth driveshaft operation was achieved despite the increased load of the cutter. With appropriate steering and positioning capability, such a device could be constructed that would selectively remove tissue under US guidance. Downsizing will depend to some extent on the ability to construct driveshafts that are capable of delivering sufficient rotational energy to the cutting assembly with high angular fidelity.

Recanalizer hybrids

Another relatively new device potentially adaptable to US is the Vallbracht low speed rotational recanalization wire [20]. The device is capable of treating total occlusions and works by applying a slow rotational and axial force to the lesion. Although it apparently has self-directing properties and a low risk of vessel perforation, it might be possible to incorporate an imaging transducer for after-the-fact images of the recanalized lumen. We constructed a prototype rotational recanalizer with a ball shaped ultrasound transducer built into the tip to test this hypothesis. The transducer rotates in

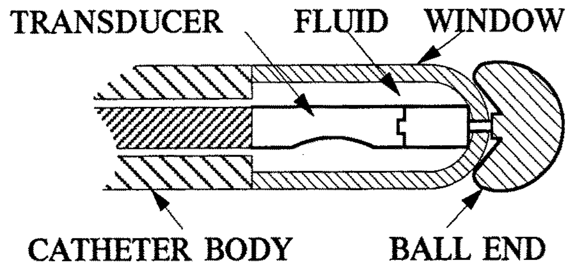

Fig. 5. Proposed US/recanalizer hybrid. Tissue is prevented from fouling transducer face by acoustic window. Ball end is driven by transducer at normal imaging speed of 600 RPM.

the sheath which is used to push the assembly forward through an obstruction. Clearance around the transducer is provided for saline flush. A rotation speed of 600 RPM was used for initial *in vitro* experiments since that was the ultrasound imaging system speed at the time. Recanalization and imaging of totally occluded cadaver artery segments was then attempted. Images showed that while the tip of the catheter worked its way through the blocked sections, some details of the vessel structure could be seen. Driveshaft artifact caused by the varying load on the system as it contacted tissue was noticeable but not objectionable. Like the side cutting atherectomy prototype, near-field clutter from blood scattering and immediately adjacent tissue limited the image quality.

We found that it is necessary to keep blood and debris away from the actual surface of the transducer where random scattering effects are most destructive to image quality, and perhaps this could be included in future devices. One possible solution to this problem might be a rotating UIC that is equipped with a transducer attached to the recanalizing ball through an end seal (Fig. 5). The transducer could then be protected from close scatterers while driving the recanalizer [21]. This device has yet to be prototyped.

Merging high-speed recanalizers such as the Rotablator or the Kensey catheter on board US imaging would be difficult since the rotational speeds exceed practical limits for artifact free mechanical ultrasound catheter imaging [22, 23].

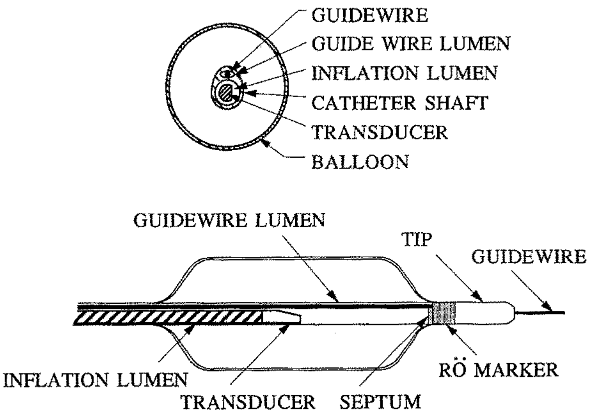

Fig. 6. Top: Cross-section of balloon ultrasound imaging catheter (BUIC). Transducer must image through catheter shaft and balloon material. Two-way attenuation through all layers is nearly 12 dB at 20 MHz. Bottom: Side view of BUIC. Transducer was positioned midway in all balloons used for clinical trials.

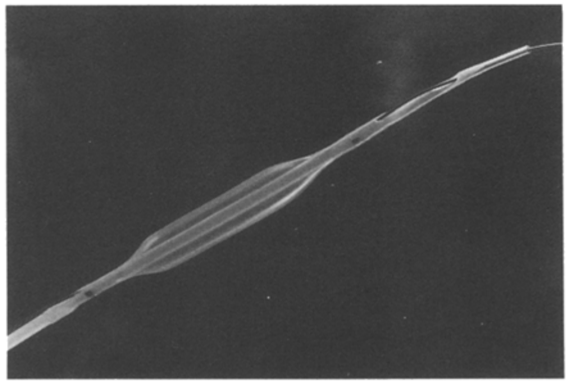

Fig. 7. Offset semicoaxial guidewire lumen, top right, allows imaging transducer to occupy inflation lumen in 7 mm × 40 mm BUIC.

Balloon angioplasty hybrids

A number of catheters that combine intraluminal ultrasound and various forms of balloon angioplasty have been proposed. Among these are mechanical rotators and non-moving arrays. A PTCA balloon with internally mounted phased or linear array assembly for obtaining real-time cross sectional views of balloon and vessel dynamics has been proposed by Griffith, et al. [24, 25]. An important aspect of their approach is the way the inventors have developed new fabrication and miniaturization of the imaging assembly [23].

Commercially, there is now a combined PTCA balloon being offered (Endosonics Corp. Pleasanton, CA, USA). This device is similar to a conventional balloon catheter, to which a synthetic aperture imaging array has been added on the shaft near the balloon [26]. It is significant for being the first commercially offered combined imaging and dilatation catheter. However, this device does not yet image through the balloon material itself. Catheters with synthetic aperture transducers have reported power outputs that are two orders of magnitude lower than those of single element devices (Physician guide and package insert, Endosonics Cathscanner PTCA Coronary Balloon Dilatation Catheter, 1990). While the low output is not necessarily indicative of low system sensitivity, this could make it difficult to successfully image directly through attenuative balloon material. Still, some changes that occur near the PTCA balloon, such as nearby vessel caliber, have been observed in real time. Despite the limitations, clinical researchers have been successful in obtaining pre and post-angioplasty images [27].

We supposed that imaging directly through the balloon would be advantageous, and that given the state of development at that time, a reasonably sized angioplasty balloon could be modified to accept an imaging transducer without loss of utility. The *Balloon-Ultrasound Imaging Catheter* (BUIC) was designed to test this assertion and provide on line images of previously unobserved dynamic conditions during angioplasty.

A dual lumen polyethylene dilatation catheter with guidewire capability was used as a design basis. Size of deflated profile, balloon size and imaging performance has to balance against the need for safe delivery to the lesion without the need for a large introducer. To accomplish this, the imaging transducer was configured to occupy the inflation lumen of the balloon, with sufficient clearance around the driveshaft for fast inflate/deflate (Fig. 6). A 20 MHz transducer with a small outside diameter (0.040″ diameter, 4.8 F Sonicath CV TM, Mansfield Scientific Corp. Watertown, MA, USA) was located in the balloon midsection. Distal friction loading of the driveshaft, known to reduce mechanical artifact by causing the driveshaft to operate in its most torsionally stiff condition, had to be sacrificed in order to preserve generous inflation area. As a compensating measure, a prestressing process was used to reduce mechanical noise and potential driveshaft artifact [21]. Finally, a fluid tight seal added to the proximal driveshaft permitted transducer rotation during balloon pressurization.

Several acoustically transparent balloon materials are available but all exhibit considerable acoustic attenuation. While polyethylene balloons exhibit the lowest attenuation and the best acoustic impedance match to blood of the high strength balloon materials, recent research suggests that it will be possible to acoustically modify other balloon materials, such as polyester, by co-extrusion (layering) techniques. In lieu of these potential developments, powerful transducers and high gain electronics are needed. By comparison, the acoustic window found in the diagnostic ultrasound catheter product (Sonicath, TM, 6F, Boston Scientific Corp. Watertown, MA, USA) yields a 2–4 dB one-way loss at 20 MHz, which is as low as can be easily realized using conventional polyethylene catheter materials and still maintain sufficient tip and window tensile strength. Similarly, a polyethylene balloon material with a 6 Atm working pressure measures approximately 3 dB one-way attenuation at 20 MHz, which is in addition to any catheter shaft and guidewire lumen attenuation. Figure 7 shows the first BUIC used for animal studies and early human clinical trials. Conservatively rated balloon parameters (thick materials) and other factors contributed to a deflated profile requiring a minimum 9F introducer sheath. A second generation device has been built with a 7F deflated profile.

BUIC clinical investigation

Following a series of laboratory tests and animal trials, the BUIC was used at one investigational site to treat 10 patients with peripheral vascular disease [28]. The object of the study was to compare imaging and measurement capabilities of the BUIC with that of conventional UICs, measure recoil at the site of dilatation, and to observe plaque fracture during the course of balloon inflation. The 7 mm and 8 mm × 4 cm balloon catheters were fitted with 20 MHz transducers, rotary seals, and inflation side arms. Radiopaque markers were positioned at the proximal and distal end of each balloon. Transducers were positioned midway in all balloons. Sterilization was accomplished with cold ETO gas, followed by aeration.

BUICs were prepared by an air purge accomplished by insertion of a venting needle in septum located at the distal end. While saline/contrast mix was injected into the side arm, distal air was expelled, and removal of the needle automatically resealed the distal septum. Remaining trapped air bubbles were removed by subsequent inflations and deflations. Finally, BUIC operation was tested by making the connection to the imaging console (Diasonics IVUS TM, Milpitas, CA) and briefly imaging in a bath of sterile saline.

After diagnostic images were obtained of the stenoses using 6F (non-balloon) UICs, all BUICs were introduced over an 0.018″ guidewire and through either a 9F or 10F introducer sheath. It was necessary to slightly pressurize the BUIC with saline/contrast mix (less than 1 Atm) in order to establish acoustic contact with the internal transducer and obtain pre-inflation images. Usable pre-PTA images and luminal measurements were obtained this way in 8 out of 10 patients, while the remaining 2 resulted in suboptimal images due to the presence of residual air bubbles.

On-line imaging during balloon inflation was available in all 10 cases. Plaque fracture, identified as a discontinuity of the luminal/intimal boundary, was observed through the balloon material at less than 2 Atm in 6 out of 10 patients. Asymmetric expansion and sudden yielding effects were also appreciated. At full inflation, maximum balloon diameter was recorded. During subsequent deflation, quality of elastic recoil, where present, was easily discerned. At full or nearly full deflation, post-PTA images were satisfactory in 9 out of 10 patients and yielded adequate luminal measurements which were compared to diagnostic UIC and angiographic measurements. Slight re-filling of the balloon (less than 1 Atm) to maintain fluid/transducer con-

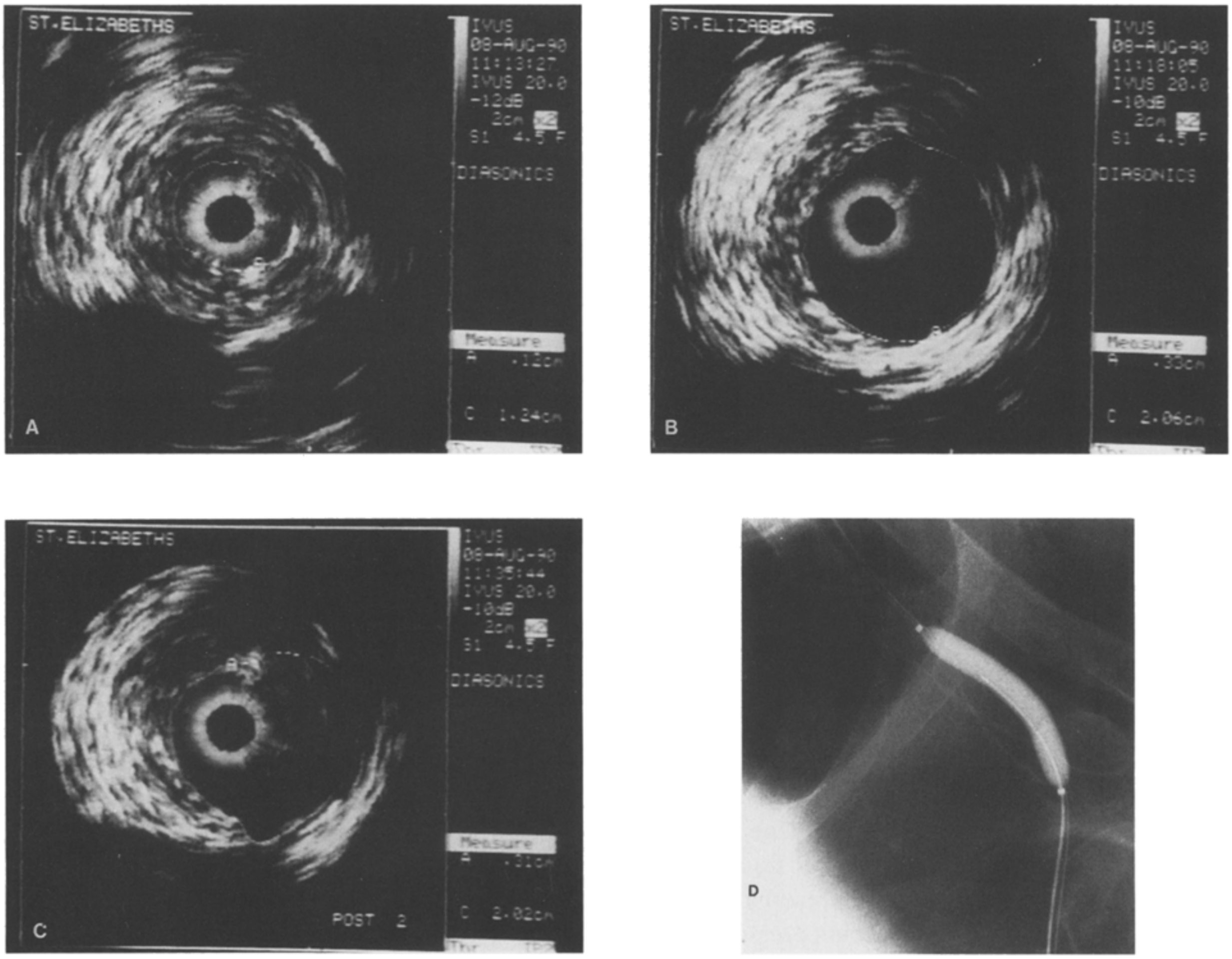

Fig. 8. A, BUIC pre-inflation in left iliac artery (XSA = 0.12 cm^2). B, At full inflation. Real time images showed a sudden increase in luminal area at about 2 Atm. Relative movement of flap end (6 o'clock), noticeable as balloon inflated. (Maximum inflated area = 0.33 cm^2). C, Post-PTA image through deflated balloon (XSA = 0.31 cm^2). D, Asymmetric position of the imaging transducer in X-ray of fully inflated BUIC.

tact was helpful in restoring image quality in cases where residual air that had been trapped inside the balloon came in contact with the transducer face. The relatively thin and sonolucent balloon perimeter was not directly visualized with US except in a few instances where the deflated balloon creases produced weak random specular reflections. In stages where balloon to lumen contact was not made, US visualization of blood flow outside of the balloon was used to delineate the stage and rate of inflation/deflation. Where balloon to lumen contact was established, as was typical, through-the-balloon imaging provided views of the outward motion of the expanding vessel wall and the contrast between the sonically clear inflation fluid and the surrounding tissue.

Figure 8 shows the cross-sectional US images obtained with one BUIC at pre-, full and post-inflation stages, and the corresponding X-ray image at full inflation.

Results and conclusions

Hybridization with US was attempted on four different therapeutic interventional modalities. The adaptability of these interventions with mechanically scanned diagnostic US technology similar to that in current clinical use was evaluated, and their potential to be usefully guided by integrated US was assessed. Our experiments with the PAAC system demonstrated one way to provide coincidence of laser action and scan plane. *In vitro* imaging gave some insight into the probable echographic appearance of the gas by-products of photo-acoustic ablation, and showed us that significant degradation of image quality by gas bubbles was likely in the absence of adequate vessel perfusion. Further, we found that complete access to the lesion was prevented by catheter tip shape resulting from a perpendicular scan and forward firing geometry.

In vitro experiments with a prototype combined atherectomy/US hybrid suggested that the potential for using US to guide this modality was more favorable, in part due to the physical similarities of mechanically scanned catheter US systems and current directional atherectomy/biopsy products. Fine positioning of the device relative to a tissue phantom material was achieved under US guidance, and removal of phantom tissue was accomplished using a US transducer modified with a cutting edge. Radial location of target tissue was controlled manually and distinct echographic identification of the excised area was made. Reverberation artifacts from the hyperechoic metallic housing and adjacent tissue were identified and possible solutions to eliminate these have been offered. Mechanical artifact from rotational inconsistencies was minimal, suggesting that present transducer and driveshaft designs have adequate torsional rigidity for both imaging and cutter rotation functions.

Interesting but inconclusive results were obtained from *in vitro* use of the combined US and low speed recanalizer. Image quality degradation from close tissue contact tends to confirm our experience with the atherectomy/US prototype.

The most promising results were obtained with the BUIC device. Animal and clinical use of the BUIC demonstrated that certain commonly used angioplasty balloons are sufficiently sonolucent for through-balloon imaging of arterial structure with existing mechanically scanned intravascular ultrasound transducers. Acoustic attenuation of one high-strength balloon material is similar to that found in diagnostic UICs, and balloon geometry is conveniently compatible with 360 degree rotary scanning systems, obviating the need for special measures to achieve image plane coincidence. Reflection artifacts from residual air within the balloon were experienced and their effects were shown to have a minor negative impact on overall imaging capability. The luminal measurement capability of the imaging system was retained, and good mechanical performance of the transducer and driveshaft was demonstrated in the absence of a distal frictional load, as was the ability to utilize the inflation lumen of an angioplasty catheter as the access port for a miniature ultrasound transducer. Most importantly, we confirmed that single-plane images could be obtained through the mid-section of the angioplasty balloon at all times during the course of the angioplasty procedure, and pre-inflation, inflation and post-inflation luminal results such as plaque fracture and instant elastic recoil could be immediately monitored with real-time US.

Discussion and future directions

After review of the experiments and clinical results, we developed a general list of requirements for the ideal mechanically scanned transducer and imaging system for use in US hybrids.

* The transducer and electronics should be robust. Proposed atherectomy devices utilize the driveshaft to exert an axial cutting force in addition to the rotating force. Tensile strength of the assembly has to be high without sacrificing rotational fidelity.
* Transducer modularity is required for various balloon sizes and configurations to be accommodated.
* Transducers must have adequate power and sensitivity. Balloons that are strong enough to perform reliable angioplasty without failure are usually only fair transmitters of ultrasound energy.
* Direct contact of the transducer element to surrounding tissue should be avoided. Near field

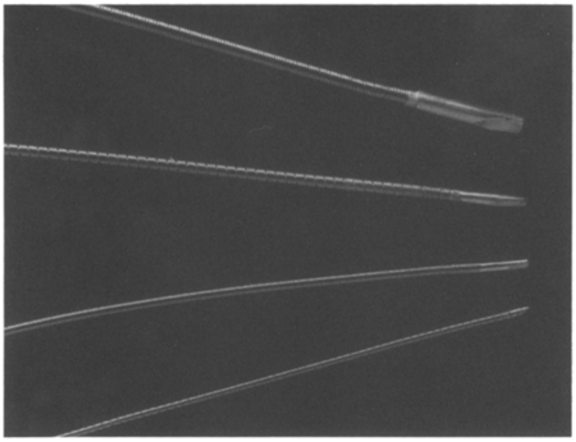

Fig. 9. Ultrasound transducers are getting smaller. Top-bottom; 0.088″ for 9F, 12.5 MHz catheter, 0.054″ for 6F, 20 MHz, 0.042″ for 4.8F, 20 MHz, and 0.031AI for 3.5F, 30 MHz.

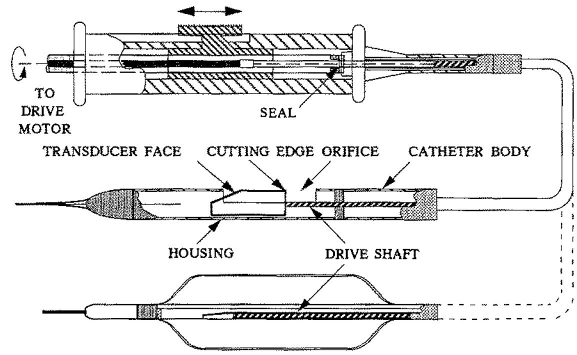

Fig. 10. Both US/atherectomy and US/balloon hybrids may require relative adjustment of transducer for full length views and 3D reconstruction. Modified Roberts handle (top) is equipped with a pressure seal to allow transducer positioning during atherectomy or angioplasty.

scattering by debris is destructive to image quality.

* The catheter should be immune to electrical interference. Lasers, RF generators and electric driving motors are prolific RFI emitters. A system solution that employs aggressive shielding with RFI suppression is needed.
* Guidewire-sized transducers will avoid making the hybrid device significantly larger than its conventional counterpart. Miniaturization of imaging transducers is a continuing trend (Fig. 9).
* Resolution should be adequate for the particular therapy. Laser ablation might require high resolution near the catheter tip, balloon angioplasty may not. Coincidence of the image plane and the therapeutic activity is desirable.
* The imaging console should be flexible. A range of operating speeds may allow better operation of cutters and recanalizers. Higher (30 MHz) and lower (10–12 MHz) frequencies should be available to match the imaging requirements of the hybrid devices in varied luminal sizes.

Our own work in interventional ultrasound has focused mainly upon the development of diagnostic US catheters that can be used with conventional forms of therapy. Much of the challenge has been to produce catheters that have handling characteristics familiar to users. Complicated user interfaces compound this challenge, and future US and therapeutic hybrids like laser angioplasty may have to be integrated with the imaging system so that their operation is intuitive. The interpretation of luminal conditions through intravascular ultrasound is in its infancy. Though some of the examples given may in the future become standards in the interventionalist's armamentarium, at best they can only begin to treat the very wide range of diseased conditions, sizes, shapes and luminal features to be found [29], and the echographic appearance of these conditions is just beginning to be understood with any degree of certainty. Further research to correlate the effects of the various interventions with their echographic appearance must continue along the lines of Gussenhoven et al, who have shown that certain interventions, such as spark erosion, may produce signature images [30].

We have experimented with and reviewed a few of the hybrid US catheter devices currently in use or being contemplated; no doubt many more are possible.

Intravascular US has been shown to be particularly useful in assessing the need for stent implantation in cases where control of large intimal flaps is required following angioplasty [31]. An extension of the combination of US with balloon angioplasty is in the deployment of intravascular stents. These stents are generally placed under fluoroscopic guidance, however, more flexible stents from several manufacturers have less than adequate radiopacity. The thinnest and most flexible stent should be easily detected with US, and equipping a device like the BUIC with a stent may allow the future interventionalist to assess the expansion of the stent prior to removal of the placement balloon. US observation of a defective stent placement and stent recoil through its entire length could indicate immediate subsequent balloon inflations. Adding a traverse mechanism like that found in the US/atherectomy hybrid prototype has provided imaging capability through the length of the balloon in recent lab experiments (Fig. 10).

Full-length views through balloons may be particularly useful in documenting work in thermal balloon angioplasty. Lennox et al have described an RF heated thermal angioplasty balloon system that uses the saline/contrast mix within the balloon as a resistive heating element [32]. This arrangement has been shown to produce near-even temperature gradients throughout the balloon and apparently solves some of the problems with localized heating associated with other forms of hot balloon technology. Its intended use is to thermally improve vessel wall and plaque compliance and avoid the generation of large intimal flaps and subsequent medial exposure that has been linked to restenoses. Clinical researchers may be able to optimize temperature, pressure and inflation rate parameters in response to on-screen cues like plaque fracture and recoil effects seen with initial BUICs, and document immediate differences of cold vs. thermal techniques.

Another interesting combination that may be readily accomplished from existing interventional hardware is a US guided thrombectomy catheter. Recent research has shown that thrombus in the vicinity of vena caval filter placement can be identified and located with intravascular ultrasound catheters [33]. Steerable thrombectomy catheters already in use have sufficient clearance to accept small rotating transducers.

Imaging of intracardiac structures with UIC technology may supplant certain forms of transesophegeal cardiac imaging in situations where acoustic access limits detailed views of small features. Already a number of intracardiac features have been examined with UICs, and the potential to combine US imaging capability with valvuloplasty balloons and other interventional modalities used in the heart is distinctly anticipated [34].

Practical US hybrids have been used clinically, and their usefulness may well be established in a short time. Exciting new combinations are anticipated. Despite the early successes, widespread commercialization of these hybrids will have to wait until a significantly large base of diagnostic ultrasound imaging systems are in place for their sale to be economically justifiable.

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