Combination Balloon-Ultrasound Imaging Catheter for Percutaneous Transluminal Angioplasty
Validation of Imaging, Analysis of Recoil, and Identification of Plaque Fracture

Jeffrey M. Isner, MD; Kenneth Rosenfield, MD; Douglas W. Losordo, MD; Lynda Rose, BA; R. Eugene Langervin Jr., MD; Syed Razvi, MD; and Bernard D. Kosowsky, MD

Background. We investigated the hypothesis that an ultrasound transducer positioned within an angioplasty balloon could be used to perform quantitative assessment of arterial dimensions before and after percutaneous transluminal angioplasty (PTA) and to identify certain mechanical alterations consequent to PTA, including vascular wall recoil and the initiation of plaque fractures.

Methods and Results. A combination balloon-ultrasound imaging catheter (BUIC) that houses a 20-MHz ultrasound transducer within and halfway between the proximal and distal ends of an angioplasty balloon was used to perform PTA in 10 patients with peripheral vascular disease. Each PTA site was also evaluated before and after PTA by standard (nonballoon) intravascular ultrasound (IVUS) technique. In eight patients in whom satisfactory images were recorded with the BUIC before PTA, luminal cross-sectional area (XSA) of stenotic sites (0.10±0.01 cm²) did not differ significantly from measurements of XSA by IVUS (0.09±0.01 cm², p=NS). Likewise, minimum luminal diameter (Dmin) measured by BUIC (0.34±0.02 cm) was similar to that measured by IVUS (0.33±0.01 cm, p=NS). In nine patients in whom satisfactory images were recorded with the BUIC after PTA, XSA measured by BUIC (0.29±0.03 cm²) did not differ significantly from XSA measured by IVUS (0.30±0.03 cm², p=NS). Dmin measured by BUIC after PTA (0.57±0.02 cm) was also similar to Dmin measured by IVUS (0.57±0.03 cm, p=NS). After PTA, XSA and Dmin measured immediately after deflation were significantly less than balloon XSA and diameter at full inflation, indicating significant elastic recoil of the dilated site. For the nine patients in whom post-PTA images were satisfactory for quantitative analysis, including four patients in whom recoil was 39%, 46%, 50%, and 61%, percent recoil measured 28.6±7.2%. Finally, plaque fractures were identified on-line in six of 10 patients (60%); in each case, initiation of plaque fracture was observed at inflation pressures of 2 atm or less.

Conclusions. The results of this preliminary human investigation indicate that an ultrasound transducer positioned within an angioplasty balloon can be used to perform quantitative and qualitative analyses of lumen-plaque-wall alterations immediately preceding, during, and immediately after PTA in patients with peripheral vascular disease. (Circulation 1991;84:739–754)

Investigations carried out in vitro1–4 and in vivo5–9 have established the validity and feasibility of catheter-based intravascular ultrasound (IVUS) imaging. Preliminary studies performed in vitro10,11 and in patients12–16 have further demonstrated that IVUS may be particularly useful as an adjunct to percutaneous revascularization. It has previously been suggested17,18 that the latter application of IVUS might be optimized by instrumentation that incorporates both diagnostic and therapeutic functions in a

From the Departments of Medicine (Cardiology) (J.M.I., K.R., D.W.L., B.D.K.), Radiology (R.E.L.), Surgery (Vascular) (S.R.), and Biomedical Research (L.R.), St. Elizabeth’s Hospital, Tufts University School of Medicine, Boston, Mass. Supported in part by grants from the National Institutes of Health (HL-40518), Bethesda, Md.; the Eleanor Dana Charitable Trust, N.Y.; and the Women’s Aid for Heart Research, Boston, Mass.

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single catheter. Accordingly, the present study was designed to investigate a combination balloon-ultrasound imaging catheter (BUIC) in patients undergoing percutaneous revascularization. The study had three specific goals: 1) to determine the relation between ultrasound measurements obtained through an angioplasty balloon and those obtained by a standard (nonballoon) IVUS catheter, 2) to assess the extent of immediate recoil at the site of balloon dilation, and 3) to identify the onset of plaque fractures developing on-line during balloon inflation.

Methods

Catheter

The BUIC\(^3\) (Boston Scientific, Watertown, Mass.) used in the present clinical investigation is shown in Figure 1. The catheter shaft is 8F and made of nonbraided polyethylene. A dedicated guidewire port at the distal end of the catheter accommodates guidewires up to 0.019 in. in diameter. The guidewire passes from the entry port to a side exit port, back through a 4.5-cm-long dedicated lumen under the balloon, and to an exit port positioned 1 cm proximal to the balloon. The distance from the distal tip to the proximal guidewire exit port measures 7 cm. A centrally positioned inflation and transducer lumen is carried from the distal end of the balloon to the proximal connector and inflation side arm. The proximal connector contains a rotary seal that allows fluid pressure to be held while using the same lumen for the rotary shaft and imaging crystal. Balloons were made of polyethylene and measured 4 cm in length and 7 or 8 mm in diameter. The same inner lumen used for inflation and deflation of the balloon is also used to house a rotary drive shaft with a single-element transducer at its tip.

The balloon material is designed to impedance-match the inflation fluid and surrounding tissue efficiently and permits ultrasound transmission at less than 6-dB one-way attenuation. A 6-atm working inflation pressure limit was calculated from existing balloon data and verified with standardized balloon bench testing protocols that conservatively set working pressure below burst pressure. Introduction of a nominal volume of fluid (less than 1 ml at 0 atm) allows generally artifact-free acoustic coupling between the transducer face and the balloon body; for catheters used in the present study, the balloon was centered over the transducer so that cross-sectional images could be obtained through the balloon’s midsection. Preliminary studies carried out in laboratory animals (J.M. Isner and D. Gal, unpublished observations) demonstrated that image acquisition was independent of the type and concentration of fluid used to fill the balloon. A 33% mixture of saline and contrast media was used to fill the BUIC in the present study. Nominal transducer center frequency of the current catheter is 20 MHz with a fractional bandwidth of approximately 45%. The transducer aperture is 1 mm laterally, and the lens are focused to an average distance of 2 mm. Depth of field is variable between 0.7 and 4.5 mm. Beam spread is noticeable within the field of view. Average resolutions of 400 \(\mu\)m laterally and 200 \(\mu\)m axially are realized within a 2-mm zone around the transducer area.

The catheter was used with an imaging console capable of 20-MHz imaging and 360\(^\circ\) scans (Diasonics, Milpitas, Calif.) previously described in detail.\(^4\) Briefly, the pulse repetition frequency is 10.2 kHz, the number of scans per second is 10, and the number of vectors scanned in one revolution is 1,024. Vectors were converted, processed, and displayed through a real-time scan converter with composite video output that allowed images to be archived on videotape or on a multifORMAT camera for later study.

Patients

Patients undergoing percutaneous revascularization for peripheral vascular disease were asked to participate in this clinical investigation according to a protocol approved by the Human Investigations Review Committee of St. Elizabeth’s Hospital of Boston. Because preclinical animal studies had indicated that the deflated profile of the angioplasty balloon required an introducer sheath with a minimum diameter of 9F to safely remove the BUIC, patients were excluded from consideration if the site and extent of vascular disease precluded use of such a sheath.

Certain clinical data, including the site and extent of the therapeutic intervention performed in the 10 patients in the present study, are listed in Table 1.

The BUIC was used to achieve revascularization in 10 patients with peripheral vascular disease. These sites included the common iliac artery in six patients, the external iliac artery in three, and the cephalic vein in one. Two sites were totally occluded and required guidewire recanalization before use of the BUIC. The remaining eight sites were narrowed by 52–99% in angiographic luminal diameter. Balloon dilation was performed exclusively using the BUIC at five sites; one site required predilatation with a lower-profile balloon catheter, whereas in the remaining four, supplemental dilatation was performed with an alternate balloon angioplasty catheter.

Technique

In the nine patients with iliac disease, an introducer sheath (9–10.5F, Cordis, Miami, Fla.) was inserted in retrograde fashion into one or both common femoral arteries. Patients were then fully heparinized to maintain the activated clotting time at 300 seconds or longer. A 5F pigtail catheter was then advanced into the abdominal aorta via a 0.035-in. angled Glidewire\(^5\) (Terumo, Piscataway, N.J.). The wire was then removed to allow pressure measurements to be obtained proximal and distal (sheath side-arm) to the lesion. A 0.018-in. Flex-T guide wire (Advanced Catheter Systems, Mountainview, Calif.) was then advanced via the 5F pigtail catheter into the aorta, and the pigtail catheter removed. A standard
FIGURE 1. Photograph showing design of balloon ultrasound imaging catheter (BUIC) used in the present study. Top panel: Photograph showing catheter wire guided with monorail design; wire enters distal tip of catheter, exits through the side port, reenters via dedicated port under balloon, and exits port 1 cm proximal to balloon. Middle panel: Cine frame of deflated BUIC showing distal transducer tip positioned halfway between radiopaque balloon markers. Bottom panel: Cine frame of BUIC fully inflated.
6.0F IVUS (nonballoon catheter) (Boston Scientific)\textsuperscript{13} was then advanced under combined fluoroscopic and ultrasound guidance through the introducer sheath into the abdominal aorta. Sites of stenosis were noted in reference to numbered marks on a radiographic ruler. The nonballoon IVUS catheter was then exchanged for the BUIC. Once advanced to the site of stenosis, measurements of luminal cross-sectional area (XSA) were obtained immediately before balloon inflation, at full balloon inflation, and immediately after balloon deflation (Figures 2 and 3). The BUIC was then reexchanged for the nonballoon IVUS catheter, which was advanced to the site of balloon inflation to inspect and measure the dilated artery. The latter catheter was then reexchanged for the 5F pigtail catheter, which was again used to perform pressure measurements and/or diagnostic angiography. In one patient (8; Table 1), both common iliacs were dilated simultaneously ("kissing balloon" technique) using a BUIC for one side and a standard angioplasty catheter for the contralateral artery. In another patient (9; Table 1), access to the site of a left common iliac occlusion was gained from the contralateral side.\textsuperscript{20}

In the patient (7; Table 1) with serial stenoses of the left cephalic vein, a 10F introducer was placed percutaneously into the left brachial vein. The IVUS and BUIC catheters were then advanced to the distal stenosis over a 0.018-in. Flex-T wire, and serial ultrasound examination and balloon inflation were performed as described above. Serial angiograms were obtained by injection of contrast media through the sheath side arm; serial pressure gradients were obtained using the side arm of the sheath (distal pressure) and a 5F pigtail catheter advanced over the 0.018-in. Flex-T wire to the innominate vein (proximal pressure).

**Imaging**

For both the BUIC and the nonballoon IVUS catheters, images were recorded on 1/2-in. videotape. The size of the recorded image was magnified \( \times 4 \) or \( \times 8 \), depending on the size and detail required of the subject artery. Contrast was typically optimized for gray-scale quality, which permitted recognition of blood flow; further adjustments were made according to the target of interest. Brightness was attenuated as needed to accommodate extensive calcific deposits. Injection of an agitated saline bolus was performed to enhance definition of plaque fracture sites and/or dissections resulting from balloon inflation.

Measurements of luminal diameter and XSA before and after balloon inflation and of balloon diameter and XSA were performed using custom-designed software included in the imaging console. All measurements were recorded from primary, nonpost-processed images, using the single frame that best demonstrated the luminal-intimal boundary. Interobserver variation was analyzed by having three experienced observers independently measure luminal diameter and XSA from 13 images (26 measurements per observer for a total of 78 measurements) recorded among these 10 patients.

Percent recoil was determined for each balloon inflation performed with the BUIC by calculating the ratio of luminal diameter and XSA, respectively, immediately after balloon deflation to balloon diameter and XSA measured on-line at full inflation (6 atm).

Asymmetry of balloon inflation was assessed according to movement of the expanding arterial walls with regard to transducer position during balloon inflation. Asymmetry was judged to be moderate or severe when movement of one point along the circumference of the wall exceeded movement of the opposite point on the arterial wall (along a diameter drawn through the transducer) by a factor of 2:3 and more than 3, respectively.

Identification of the onset of plaque fracture was made by analysis of BUIC recordings made during each

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BUIC, balloon ultrasound inflation catheter; DN, diameter narrowing; FCI, functional classification; ABI, ankle-brachial index; Pre, before angioplasty; Post, following angioplasty; NA, not applicable; ND, not done; REI, right external iliac; LCI, left common iliac; LCV, left cephalic vein; RCI, right common iliac; R, retrograde; k, "kissing balloon" technique; C, contralateral.
**Figure 2.** Typical sequence of images recorded from balloon ultrasound imaging catheter (BUIC) before, during, and after percutaneous transluminal angioplasty (PTA) (patient 10; Table 1). Top left panel: Image recorded from BUIC (through balloon) immediately before first inflation demonstrates stenotic lesion of left common iliac artery. Top middle and right panels: Images recorded from BUIC at 3 (middle) and 6 (right) atm of inflation pressure; preinflation luminal cross-sectional area (A) is indicated by circle inscribed peripheral to ultrasound transducer (*). Note asymmetric inflation of balloon toward less severely diseased portion of arterial (2 to 6 o'clock). Bottom left panel: Image recorded from BUIC immediately after balloon deflation; although luminal cross-sectional area has been augmented, there is loss of gain achieved at full balloon inflation (area [A] indicated by circle inscribed peripheral to transducer). Bottom middle panel: Image recorded through balloon at full inflation 2; inscribed circle indicates planimetered balloon area (A). Balloon inflation is again asymmetric. Bottom right panel: Image recorded immediately after deflation; injection of agitated saline has been used to confirm final luminal cross-sectional area indicated by inscribed circle.
balloon inflation in conjunction with simultaneous audio notation of balloon inflation pressure. Plaque fractures were defined as a discontinuity in the circumferential line identifying the luminal-intimal boundary. Fractures identified during balloon inflation were confirmed by review of the postdeflation BUIC recordings and nonballoon IVUS recordings.

The presence of calcific deposits was appreciated as a combination of high-intensity ultrasound signals associated with “shadowing” of the subjacent arterial wall.

**Angiographic Analysis**

Angiograms recorded before and after balloon dilation were analyzed quantitatively for percent luminal diameter narrowing using caliper measurements of the target stenoses in the obliquity disclosing the minimum luminal diameter (\(D_{\min}\)).

**Statistical Analysis**

Data are presented as mean±SEM values. Two-tailed Student's paired t test was used to compare measurements recorded using BUIC with those recorded using IVUS as well as serial measurements recorded with either. A probability value of 0.05 was considered to distinguish statistically significant from statistically insignificant results.

**Results**

**Measurements of Luminal Cross-sectional Area and Minimum Diameter Before Balloon Inflation**

Measurements recorded from both the BUIC and the IVUS before angioplasty in the 10 patients are listed individually in Table 2.

**Image quality.** In eight of 10 patients, images recorded from the BUIC were sufficiently satisfactory to permit quantitative analysis of \(D_{\min}\) and luminal XSA before PTA. In the two remaining patients, artifacts resulting from subtotal evacuation of air from the angioplasty balloon and/or electrical interference compromised the diagnostic quality of the recorded image. Satisfactory images were ob...

**Figure 3.** Serial images recorded from balloon ultrasound imaging catheter (BUIC) before, during, and after percutaneous transluminal angioplasty (PTA) of common iliac arterial stenosis (patient 3; Table 1). Top left panel: Image recorded from BUIC immediately before balloon inflation demonstrates pre-PTA cross-sectional area, indicated by inscribed circle. Subsequent images demonstrate serial expansion of balloon cross-sectional area recorded from BUIC during inflation 1 at 1.5, 2.0, 4.0, and 6.0 atm. The pair of images recorded at 6 atm demonstrates sudden yielding of arterial wall after several seconds at given inflation pressure; note movement of calcified (Ca) plaque toward arrow, the position of which was not changed from first to second image recorded at 6 atm. Bottom panels: Images illustrating cross-sectional area of BUIC at full inflations 2 and 3 and final luminal cross-sectional area recorded from BUIC immediately after balloon deflation.
tained from examination with the nonballoon IVUS in all 10 patients.

**Luminal XSA.** For the eight patients in whom satisfactory images were recorded with the BUIC before PTA, luminal XSA (mean±SEM) measured at the site of intended PTA was 0.10±0.01 cm² (range, 0.06–0.15 cm²). Measurement of luminal XSA in these eight patients at the same site before PTA using the IVUS was 0.09±0.01 cm² (range, 0.05–0.15 cm²). The measurements recorded by BUIC and IVUS were not significantly different (p=0.52). The mean difference between BUIC and IVUS measurements of luminal XSA in these eight patients was 0.006 cm²; this represents 6.4% of the pre-PTA measurement of the XSA using the IVUS.

**Luminal D min.** In the same eight patients, D min measured by BUIC before PTA was 0.34±0.02 cm (range, 0.25–0.40 cm), which is similar to measurements recorded at the same site using the IVUS (0.33±0.01 cm; range, 0.26–0.38 cm) (p=0.46). The mean difference between BUIC and IVUS measurements of D min was 0.01 cm; this represents 2.9% of the mean value recorded by IVUS before PTA.

**Measurements of Balloon Dimensions at Full Inflation**

The maximum diameter and XSA for balloon inflation measured on-line from the BUIC in each of the 10 patients are listed in Table 2. With one exception (patient 9; Table 2), maximum diameter of the BUIC balloon at full inflation (6 atm) was slightly less than nominal balloon diameter. For the four patients in whom an 8-mm-diameter balloon was used, balloon diameter at full inflation was 7.3±0.2 mm (range, 6.8–7.9 mm); corresponding balloon XSA was 43.5±2.5 mm² (range, 38–50 mm²). For the remaining six patients in whom a 7-mm-diameter balloon was used balloon diameter at full inflation was 6.5±0.2 mm (range, 6.1–7.2 mm); corresponding mean XSA was 34.2±1.6 mm² (range, 31–42 mm²).

**Measurements of Luminal XSA and D min After Balloon Deflation**

Measurements recorded from the BUIC and IVUS catheters after PTA in all 10 patients are listed individually in Table 2.

**Image quality.** In nine of 10 patients, images recorded from the BUIC after the final balloon dilation were sufficient to permit quantitative analysis of post-PTA luminal XSA and D min. In the remaining patient, artifacts resulting from a small air bubble interfered with accurate assessment of arterial dimensions after PTA. Again, satisfactory images were obtained from examination with the IVUS in all 10 patients.

**Luminal XSA.** For the nine patients in whom satisfactory images were recorded with the BUIC after PTA, luminal XSA was 0.29±0.03 cm² (range, 0.18–0.44 cm²). Measurement of luminal XSA in these nine patients at the same site after PTA using the IVUS was 0.30±0.03 cm² (range, 0.17–0.47 cm²). The measurements recorded by BUIC and IVUS were not significantly different (p=0.32). The mean difference between BUIC and IVUS measurements of post-PTA luminal XSA in these nine patients was 0.009; this represents 3.0% of the post-PTA measurement of the same site recorded using the IVUS.

**Luminal D min.** In the same nine patients, D min measured by BUIC after PTA was 0.57±0.02 cm (range, 0.44–0.63 cm), which is similar to D min measured at the same site from the IVUS (0.57±0.03 cm; range, 0.45–0.66 cm) (p=0.82). The mean difference between BUIC and IVUS measurements of D min was 0.003; this represents 0.5% of the post-PTA IVUS measurement.

Interobserver variability was determined for 13 images in which measurements of both XSA and D min were performed independently by three observers. For vessel XSA, mean coefficient of variance was 6.05%. For vessel D min, mean coefficient of variance was 4.77%.
Recoil

Recoil was evaluated as a function of both balloon diameter and balloon XSA at full balloon inflation for the nine patients in whom post-PTA images were satisfactory for quantitative analysis (Table 3 and Figures 4 and 5). For those patients in whom multiple inflations were performed at the same site with the BUIC, the extent of recoil was determined for each balloon inflation/deflation cycle.

Recoil as a function of balloon diameter. For inflation 1 (n=9), the D_{min} of the vascular lumen immediately after balloon deflation (0.50±0.04 cm) was significantly less than the diameter of the fully inflated balloon (0.63±0.03 cm, p=0.03). Likewise, for inflation 2 (n=8), D_{min} measured immediately after balloon deflation (0.51±0.03 cm) was less than that measured for the fully inflated balloon (0.65±0.02 cm, p=0.004).

For the total group of nine patients, recoil expressed as a percent of balloon diameter at full inflation was 19.1±7.0% after the first inflation, 21.5±4.8% after the second inflation (eight patients), and 19.0±7.1% after a third inflation (four patients). For the eight patients in whom two inflations were performed, percent recoil

![Figure 4](http://circ.ahajournals.org/)

**Figure 4.** Bar graphs of magnitude of recoil measured by balloon ultrasound imaging catheter (BUIC) as function of minimum luminal diameter (D_{min}) and cross-sectional area (XSA). For inflation 1 (n=9), D_{min} of vascular lumen immediately after balloon deflation (0.50±0.04 cm) was significantly less than diameter of fully inflated balloon (0.63±0.03 cm, p=0.03); XSA was likewise reduced from 0.33±0.02 to 0.25±0.03 cm² (p=0.03). For inflation 2 (n=8), D_{min} measured immediately after deflation (0.51±0.03 cm) was less than that measured for fully inflated balloon (0.65±0.02 cm, p=0.004); XSA was also reduced to 0.28±0.03 from 0.35±0.01 cm², although this difference did not achieve statistical significance.

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D_{min}, minimum diameter; XSA, cross-sectional area.

Recoil could not be accurately calculated in patient 5 in whom postdeflation images were unsatisfactory for measurements of D_{min} and XSA.
after inflation 1 (20.4±7.8%) did not differ significantly from recoil after inflation 2 (21.5±4.8%) (p=0.84). The number of patients undergoing a third inflation was too few to permit meaningful statistical comparison with recoil observed after inflations 1 and 2.

Assessed individually, recoil measured as a function of balloon diameter was observed in seven of nine patients (77.8%) after inflation 1 and ranged from 6% to 54%; the latter, most severe instance of elastic recoil was observed in the venous limb of an arteriovenous dialysis fistula (Figure 5). In one patient, no recoil was observed after inflation 1. In another patient, arterial diameter after inflation 1 exceeded balloon diameter at full inflation (“negative” recoil). After inflation 2, recoil was observed in eight of eight patients (100%) and ranged from 2% to 46%. After inflation 3, recoil was observed in four of four patients (100%) (2–35%).

Recoil as a function of balloon XSA. For inflation 1 (n=9), luminal XSA immediately after balloon deflation was 0.25±0.03 cm², significantly less than XSA of the fully inflated balloon (0.33±0.02 cm², p=0.03). For inflation 2 (n=8), luminal XSA after deflation (0.28±0.03 cm²) was reduced from XSA at full inflation (0.35±0.01 cm²), although the difference did not achieve statistical significance (p=0.09).

For the total group of nine patients, recoil expressed as a percent of balloon XSA at full inflation was 28.6±7.2% after the first inflation, 18.6±10.1% after the second inflation, and 21.0±9.0% after the third inflation. For the eight patients in whom two inflations were performed, percent recoil after inflation 1 (25.9±10.0%) did not differ significantly from percent recoil observed after inflation 2 (18.6±10.1%) (p=0.136).

Assessed individually, recoil was observed as a function of XSA in seven of nine patients (77.8%) and ranged from 10% to 61%; again, the latter and most extreme example was the venous limb of the dialysis fistula. In two patients, negative recoil was observed (i.e., post-PTA XSA exceeded XSA of the fully inflated balloon). In one of these patients (3 Table 3), no recoil was observed as a function of diameter. In another (6; Table 3), recoil equal to 11% in diameter was observed. Finally, in the one patient (2; Table 3) in whom negative recoil had been observed as a function of diameter, recoil as a function of XSA was equal to 11%.

After inflation 2, recoil was observed in six of eight patients (75%); negative recoil measured as a fraction of XSA was observed in two patients. In the latter two patients (2 and 3; Table 3), recoil as a function of diameter was measured as 23% and 2% respectively.

After inflation 3, recoil was observed in three of four patients (75%); in one patient with 2% diameter recoil, no recoil was observed in terms of XSA.

Analysis of a variety of anatomic features among these nine patients disclosed no specific variables that consistently distinguished the four individuals in whom recoil was most severe (patients 1, 4, 7, and 9; Table 3) from the remaining five patients.

Asymmetry

Qualitative evaluation of balloon inflation disclosed asymmetric movement of the expanding arterial walls with regard to the transducer in seven of 10 patients (70%). In two patients, movement of one point along the circumference of the arterial wall exceeded movement of the opposite point on the arterial wall (along a diameter drawn through the transducer) by a factor of 3 or more (marked asymmetry; Figures 2 and 6). In five patients, the magnitude of asymmetric expansion was equal to or more than a factor of 2 but less than 3 (moderate asymmetry). In each of these cases, balloon inflation produced an increase in luminal XSA at the expense of a less diseased arc of arterial wall, whereas a more diseased, often calcified arc of the wall resisted expansion. In one patient (9; Table 3), marked asymmetry was associated with profound recoil; in three other patients (1, 4, and 10), moderate asymmetry was associated with substantial recoil as well.

Plaque Fracture

In six of 10 patients (60%), development of plaque fracture (discontinuity in the circumferential line identifying the luminal-intimal boundary) was observed during balloon inflation (Figures 6 and 7). In each of the six cases, initiation of the fracture was observed at an inflation pressure of less than 2 atm. Plaque fractures were in each case confirmed by IVUS; furthermore, definition of the plaque fracture was typically more complete on images recorded from the IVUS than on those recorded from the BUIC.

Technical Issues

In one patient (2; Table 1), excessive oozing of blood both around the 9F introducer sheath and through the hemostasis valve of the sheath during the period of time
FIGURE 6. Images showing plaque fracture (crack) observed during balloon inflation using balloon ultrasound imaging catheter (BUIC). Top panel: Image recorded at 4 atm showing fully developed crack as seen during inflation. Middle panel: Appearance of crack immediately after balloon deflation. Bottom panel: Confirmation of crack identified with BUIC by image recorded from nonballoon intravascular ultrasound catheter (IVUS).

FIGURE 7. Images showing fracture (crack) of heavily calcified plaque during percutaneous transluminal angioplasty (PTA) using balloon ultrasound imaging catheter (BUIC). Top panel: Crack near one end of calcific bar at full balloon inflation; inscribed circle denotes cross-sectional area (A) of balloon. Middle panel: Appearance of the crack immediately after deflation of BUIC balloon. Bottom panel: Confirmation of crack identified with BUIC by image recorded from intravascular ultrasound catheter (IVUS).
that the IVUS and BUIC with their respective mono-rail wires were within the sheath resulted in the need for transfusion of 2 units of blood. In another patient, resistance encountered during removal of the BUIC through a 9F sheath deformed the distal portion of the catheter; the catheter, however, remained intact and resulted in no complication.

Clinical Follow-up

Patient 7 (in whom the most excessive recoil was observed [Figure 5]) required repeat PTA for restenosis 4 months after the initial PTA. Four patients (3, 4, 6, and 8; Table 1) underwent iliac PTA as the initial staged procedure in preparation for surgical revascularization of distal disease. Three patients (5, 9, and 10) are asymptomatic at 9, 8, 8, and 6 months’ follow-up, respectively. Patient 2 remains in New York Heart Association functional class III; he has been unable to return for treatment of distal disease because of nonvascular medical problems. Patient 1 was found to have colon cancer 4 months after PTA; he was asymptomatic with regard to claudication until his death 5 months later.

Discussion

The findings in this preliminary investigation demonstrate the feasibility and potential usefulness of in vivo catheter-based, IVUS imaging through an angioplasty balloon. The concept of combining the elements responsible for intravascular imaging with those responsible for percutaneous revascularization has been investigated previously. IVUS21 and angiography22 were both recognized as potential solutions to the problem of arterial perforation that complicated early clinical trials of non–wire-guided laser angioplasty. One such catheter, which was actually used clinically, included a dedicated lumen for vascular endoscopy in addition to the lumen housing the fiberoptic elements required to transmit laser light.23 Although this catheter retained the advantage of angiography for forward viewing, it also included the liability of requiring periodic evacuation of blood to record detailed images. Subsequent attempts to monitor laser ablation incorporated fluorescence spectroscopy in combination with a flash-lamp pumped dye laser.24 This approach eliminated the requirement for a blood-free lumen while preserving the ability to accomplish forward imaging.

More recently, attempts have been made to combine IVUS imaging with balloon angioplasty and/or mechanical atherecotomy. Mallery et al25 performed in vitro imaging with a 4.5F balloon dilatation catheter fitted with an array of eight 20-MHz transducers mounted radially around the catheter. The transducers were positioned within and halfway between the two ends of a 3.0-cm polyethylene balloon; images were recorded perpendicular to the long axis of the catheter, through the balloon. Diameter measurements of pig aorta made by ultrasound reportedly correlated well with actual measurements of the aorta itself.

Yock et al26 investigated a prototype catheter that combined a 30-MHz transducer with a modified version of the Simpson directional atherectomy catheter. Preliminary experiments performed in vitro and in vivo demonstrated that this device could be used to monitor the depth to which plaque was mechanically excised.

Although these two prototype devices, like the catheter used in the present trial, were designed so that ultrasound imaging could be performed on-line (i.e., during balloon inflation or mechanical atherectomy), Hodgson et al27 performed in vivo imaging in a series of normal canine coronary arteries with a balloon catheter on which a ring of modified phased-array transducers were positioned proximal to the balloon. The design of this device was intended to permit predilation and postdilation imaging without the requirement for multiple catheter exchanges.

The results of the present clinical investigation confirm that it is feasible to perform IVUS imaging on-line during percutaneous revascularization using a hybrid device that incorporates both diagnostic and therapeutic functions. Experience in these 10 patients has helped to clarify several technical issues. First, it was possible to obtain at least one set of diagnostic images (i.e., before or after PTA) in all 10 patients while imaging through polyethylene balloon material, the thickness of which is standard for peripheral angioplasty balloons.

As suggested from preclinical research performed in normal dogs and atherosclerotic microswine (J. M. Isner, D. Gal; unpublished observations), the nature and mixture of material used to fill the balloon had a negligible effect on the quality of image obtained. The exception to this was, of course, residual air within the balloon, which when present compromised detail required for quantitative analysis. When images recorded from the BUIC were not compromised by incomplete evacuation of air from the balloon, measurements of luminal XSA and Dmin were nearly indistinguishable from those recorded using a nonballoon ultrasound catheter; measurements recorded from the latter have been shown to correlate well with measurements derived from quantitative angiographic analysis of native normal and diseased arteries.5–8

All images in the present study were recorded with a 20-MHz transducer. Although this frequency appeared satisfactory for qualitative and quantitative analyses in both the presence and absence of an inflation balloon, it remains to be determined whether frequencies investigated in other mechanical systems—specifically, 30 MHz26 and 40 MHz2—may yield superior results.

Assessment of recoil after balloon deflation constitutes a specific application of these quantitative findings. Recoil has long been inferred to constitute a mechanical reason for loss of gain achieved during balloon inflation.28–31 More recently, several investigators have used quantitative angiographic techniques to analyze the extent to which recoil complicates standard coronary angioplasty (percutaneous
transluminal coronary angioplasty [PTCA]). Nobuyoshi et al\textsuperscript{32} performed coronary angiography routinely on 185 patients 1 day after PTCA. “Restenosis” (more than 50% loss of gain in absolute diameter assessed by cineangiography) was already present in 27 of 185 patients (14.6%) or in 27 of 237 lesions (11.4%) by 1 day and was interpreted to represent evidence of elastic recoil.\textsuperscript{32} Stenosis diameter among these 185 patients decreased from 1.91±0.53 mm immediately after PTCA to 1.72±0.52 mm 1 day after PTCA (p<0.001).

Hjemdahl-Monsen et al\textsuperscript{33} derived pressure–diameter curves from videodensitometric measurements made at incremental pressures (1–6 atm) during PTCA of 29 lesions in 27 patients. Recoil (balloon diameter at 6 atm/post-PTCA luminal diameter, >1.0) was observed in 25 of 29 lesions and ranged from 1.02 to 2.01% (mean±SD, 1.35±0.33%).

Rensing et al\textsuperscript{34} performed videodensitometric analysis on 151 lesions successfully dilated among 136 patients during balloon inflation and directly after balloon deflation. Mean XSA of the inflated balloon was 5.2±1.6 mm\textsuperscript{2}, whereas mean (minimal) XSA of the dilated stenosis after balloon deflation was 2.8±1.4 mm\textsuperscript{2}. Thus, nearly 50% of the theoretically achievable XSA was lost immediately after balloon deflation. In contrast to the findings of Nobuyoshi et al, analysis of a subset of 16 patients (18 lesions) reexamined 1 day after PTCA disclosed no further reduction in minimum luminal XSA.

Finally, Lehmann et al\textsuperscript{35} prospectively evaluated 114 lesions undergoing PTCA by quantitative angiography and found that recoil (percent loss of diameter gained during maximum balloon inflation) averaged 34±23.3%, reducing calculated post-PTCA XSA from 5.65 to 3.45 mm\textsuperscript{2}.

Measurements recorded in the present investigation using IVUS confirm the preceding observations made using angiographic techniques and establish that the phenomenon of recoil is common to peripheral as well as coronary angioplasty. Furthermore, because there is a nearly unavoidable delay between balloon deflation and quantitative angiographic examination after PTCA, Rensing et al\textsuperscript{36} had raised the possibility that platelet deposition and/or nonocclusive mural thrombus frequently observed at balloon angioplasty sites postmortem could not be ruled out as the basis for apparent recoil observed angiographically. The present series of observations, in which ultrasound analysis of recoil was accomplished immediately on balloon deflation, establishes conclusively that such recoil is instantaneous. It is of interest that the one patient in this series (7; Table 3) in whom clinical evidence of restenosis has thus far been observed was the patient in whom recoil was most severe (Figure 5).

In five instances, measurements recorded with the BUIC disclosed negative recoil (i.e., luminal dimensions after PTA exceeded those of the angioplasty balloon at maximum inflation). In one case, post-PTA diameter of the arterial lumen slightly exceeded that of the balloon, whereas post-PTA XSA was slightly less than that of the balloon. In the remaining four cases, although recoil varied from 0% to 23% as a function of balloon diameter, when measured in terms of XSA, luminal area after PTA exceeded balloon area by 4–22%. Although not explicitly commented on, inspection of findings reported by Hjemdahl-Monsen et al\textsuperscript{33} and Lehmann et al\textsuperscript{35} reveals several cases in which diameter measurements made by quantitative angiography were indicative of such negative recoil. Analysis of this phenomenon in the present series of cases suggests that it results from a relatively large (but non–flow-limiting) plaque fracture; this has the previously noted effect of limiting elastic recoil.

It must be acknowledged that analysis of recoil in the present series of patients did not attempt to include consideration of the extent to which the balloon inflation medium might alter the speed of sound. If one assumes that the speed of sound is uniformly increased by as much as 5% in contrast medium, then the 33% saline-contrast mixture routinely used for the BUIC could create an error of 1.65% or less (acoustic velocity is the same for saline and blood). Although this potential error might cause underestimation of balloon diameter and XSA at full inflation, the close correspondence between measurements made by BUIC and those made by IVUS before and after PTA suggest that at least the small volume of medium in the deflated balloon did not affect these latter measurements significantly.

Furthermore, when a radial plaque fracture is associated with a circumferential extension, the resulting XSA may exceed that of the inflated balloon, despite the fact that the post-PTA luminal \(D_{\text{min}}\) along a selected minor axis is slightly less than that of the inflated balloon. Because IVUS allows direct inspection of the often complex “cracked” and/or dissected post-PTA lumen, diameter and XSA may both be assessed directly and independently.\textsuperscript{5–10} Most algorithms developed for quantitative angiography calculate XSA as a function of measured luminal diameter, and previous studies have documented that the accuracy of such algorithms may be diminished in those cases in which satisfactory orthogonal views cannot be obtained.\textsuperscript{37} Assessment of elastic recoil after angioplasty may thus be more complicated than previously appreciated; it is entirely possible that apparent recoil measured as a function of luminal diameter after angioplasty is more frequently than previously thought associated with a paradoxical increase in luminal XSA.

Parenthetically, analysis of recoil in the present investigation disclosed that balloon diameter and XSA were somewhat inconstant at a constant, nominal inflation pressure of 6 atm. Similar findings were reported by Hjemdahl-Monsen et al\textsuperscript{33}; despite the fact that all lesions were dilated with the same type of 3.0-mm balloon according to an identical inflation protocol, balloon diameter measured at maximum inflation varied from 1.6 to 3.2 mm.\textsuperscript{33} Although
selection of optimal balloon size and/or inflation schemes remains controversial, on-line ultrasound imaging of balloon inflation facilitates direct confirmation that the desired inflation dimensions have been achieved.

Finally, on-line ultrasound monitoring of balloon inflation also facilitated identification of the initiation of plaque fracture. On-line analysis of pressure-volume curves has been investigated as a means of characterizing the mechanism responsible for vascular dilation in vivo. “Cracking,” or sudden yielding of the balloon at a given inflation pressure, was less often observed than were patterns indicative of either “stretching” or “compaction.” The results of on-line ultrasound analysis of balloon inflation suggest that plaque fracture is proportionately more common than indicated by pressure-volume analysis; this is further supported by post-hoc ultrasound analyses and previously reported necropsy studies. Furthermore, in at least one patient (3; Table 1 and Figure 3), we observed what graphically would appear to correspond to “sudden yielding of the balloon [and arterial wall] at a given inflation pressure” unaccompanied by evident plaque fracture during or after PTA.

Images recorded from the BUIC disclosed that plaque fractures were initiated by dilatation at low (less than 2 atm) inflation pressures. This is consistent with previous clinical observations. Hjemdahl-Monsen et al. found that most improvement in luminal size occurred at inflation pressures of less than 2 atm. Likewise, Kahn et al. observed that full balloon expansion as determined by fluoroscopic monitoring occurred in nearly 50% of patients at inflation pressures of 4 atm or less. These findings regarding the efficacy of lower inflation pressures supplement experimental data indicating a higher incidence of mural thrombus, dissection, and intimal hyperplasia as a result of higher inflation pressures. As suggested by Kleiman et al., any technique, whether pressure-volume or ultrasound analysis, that permits immediate, on-line recognition of plaque fracture might theoretically be used to modify the remainder of the dilatation procedure in an attempt to prevent the development of a flow-limiting dissection. Subsequent clinical investigations of devices that combine imaging and therapeutic applications may allow more detailed assessment of this hypothesis.

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