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Methodological Problems Related to the Quantitative Assessment of Stretch, Elastic Recoil, and Balloon-Artery Ratio

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The (inflated) balloon is important to determine the extent of stretch (theoretical maximal gain in diameter or area during PTCA), elastic recoil (the loss in diameter or area immediately after PTCA), and whether under- or over-sizing (balloon-artery ratio) of the dilated lesion occurred. In these assessments, the inflated balloon is used as scaling device with assumed uniformity along its entire length. In order to assess more accurately stretch, elastic recoil, and the balloon-artery ratio, the balloon diameter was measured over its entire length with edge detection and videodensitometry in 505 lesions (453 patients). With an average inflation pressure of 8.3 ± 2.6 atm a difference between the minimal and the maximal balloon diameter of 0.59 ± 0.23 mm was measured using edge detection and 1.70 ± 0.90 mm^2 difference in area using videodensitometry. This results in large variations in the calculated stretch, elastic recoil, and balloon-artery ratio depending on the site of the balloon chosen for assessment. The mean difference ± SD between stretch and elastic recoil assessed by edge detection and videodensitometry (using the minimal luminal diameter or area of the balloon) are respectively 0.00 ± 0.19 and 0.00 ± 0.24, suggesting that both methods are appropriate.

Key words: PTCA, balloon, QCA, recoil

INTRODUCTION

Percutaneous transluminal coronary angioplasty (PTCA) is an accepted revascularization procedure for treatment of patients with stable and unstable angina pectoris and for patients with single and multi-vessel disease [1,2]. Although earlier work has drawn attention to the process of in vivo inflation of the balloon, in vivo pressure-volume relationship [3], and in vivo pressure-diameter curves [4], the quantitative analysis of the inflated balloon at the site of the stenotic lesion has not been emphasized. Visual inspection of the inflated balloon led to the assumption that, with the use of a pressure as high as 20 atm, the balloon is fully and uniformly inflated to a diameter in accordance with the manufacturer's specification.

With the introduction of computer-based quantitative analysis systems—edge detection and videodensitometry—it became possible to measure the exact diameter and area of normal and stenotic arterial segments pre- and post-PTCA as well as the balloon diameter during full inflation. However, conflicting data has been published about the correlation of post-angioplasty analysis between the two techniques [5–20].

The inflated balloon has important clinical implications since it affects the extent of 1) stretch (theoretical maximal gain in diameter or area during PTCA), 2) elastic recoil (influence the immediate post-PTCA result) [4,21,22], and 3) under- or over-sizing of the lesion (important factor in the incidence of dissections) [23–26]. In the assessment of these three parameters, the inflated balloon is used as scaling device and is presumed uniform along its entire length. However, this assumption has never been critically analyzed.

The objective of this study was to determine (using two quantitative methods) whether the balloon diameter is uniform along its entire length. In the event of non-uniformity of the inflated balloon, guidelines will be

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proposed for the selection of the balloon diameter for future quantitative studies.

MATERIALS AND METHODS

Study Population and PTCA Procedure

The study population consisted of 453 patients (505 lesions) who had undergone successful PTCA at the Thoraxcenter between June 1989 and December 1989, defined as a less than 50% diameter stenosis on visual inspection of the post-PTCA angiogram. Patients with stable and unstable angina were included; patients with acute myocardial infarction (<7 days) and patients with total occluded lesions pre-PTCA were excluded. Mean age of the patients was 56 ± 10 yr. Of the 505 lesions dilated, 146 were located in the right coronary artery (RCA), 238 in the left anterior descending (LAD), and 121 in the left circumflex artery (LC).

Medications at the time of the procedure were intravenous heparin and acetylsalicylic acid. Choice of balloon type (compliant vs. non-compliant), inflation duration, total number of inflations, and inflation pressure were left to the operator. Coronary angiograms were recorded before and after angioplasty, and during dilatation with the largest balloon size at the highest inflation pressure applied.

Quantitative Coronary Angiography

The quantitative analysis of the stenotic coronary segments and the balloon at maximal inflation pressure was carried out by the Coronary Angiography Analysis System (CAAS), which has been validated and described in detail elsewhere [7,12,13]. Examples of analyses are shown in Figure 1.

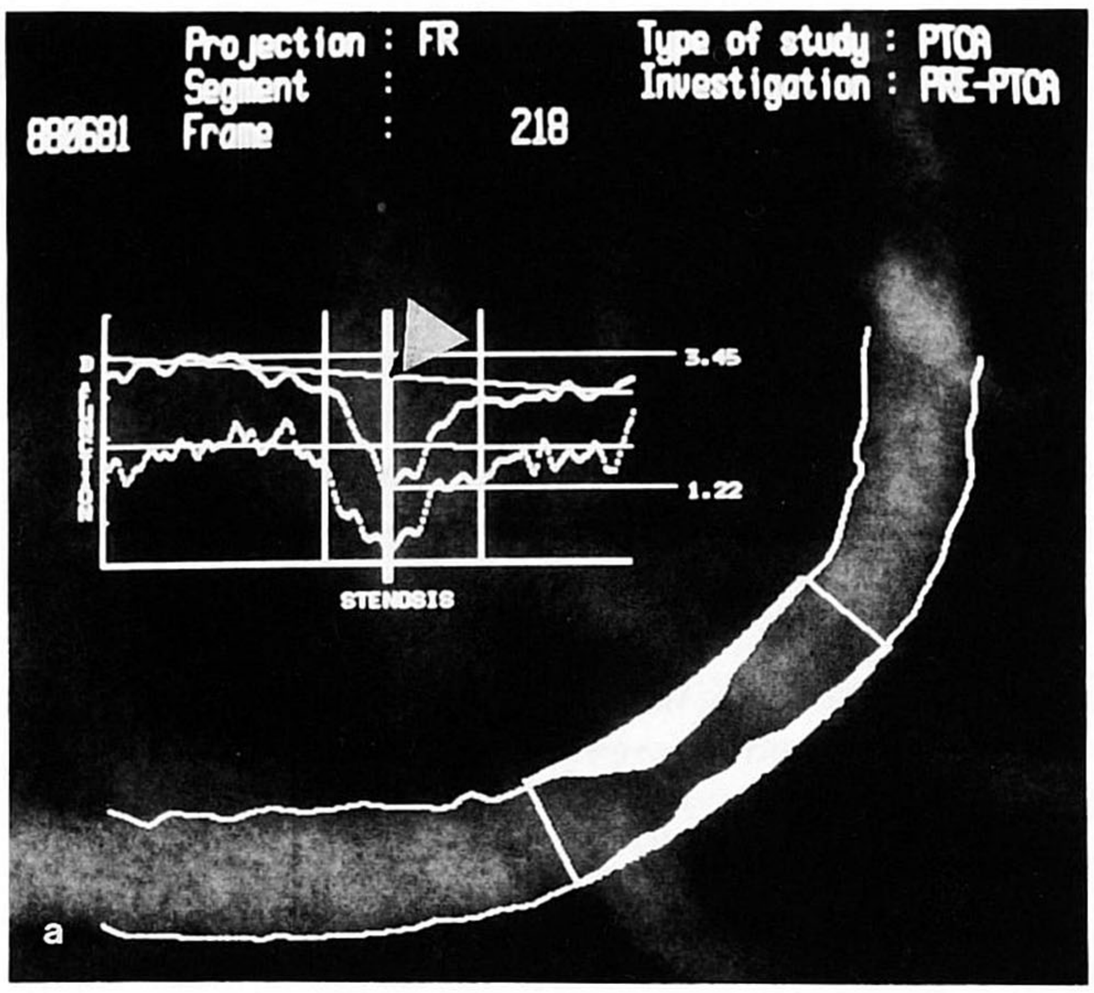
Single identical views pre-PTCA, post-PTCA, and during balloon inflation were chosen for analysis. For this purpose, the largest balloon filled with contrast was filmed during the last inflation at maximum pressure. Contrast medium (Isopaque Cerebral 280 mg/ml, Nycomed AS Oslo) that is routinely used for arteriography of the carotid arteries was selected for its high radiopacity, which enhances the automated edge detection and videodensitometric analysis. This contrast medium has a low-viscosity and therefore does not need to be diluted. Special attention was given to avoid air bubbles in the balloon when filling with contrast medium.

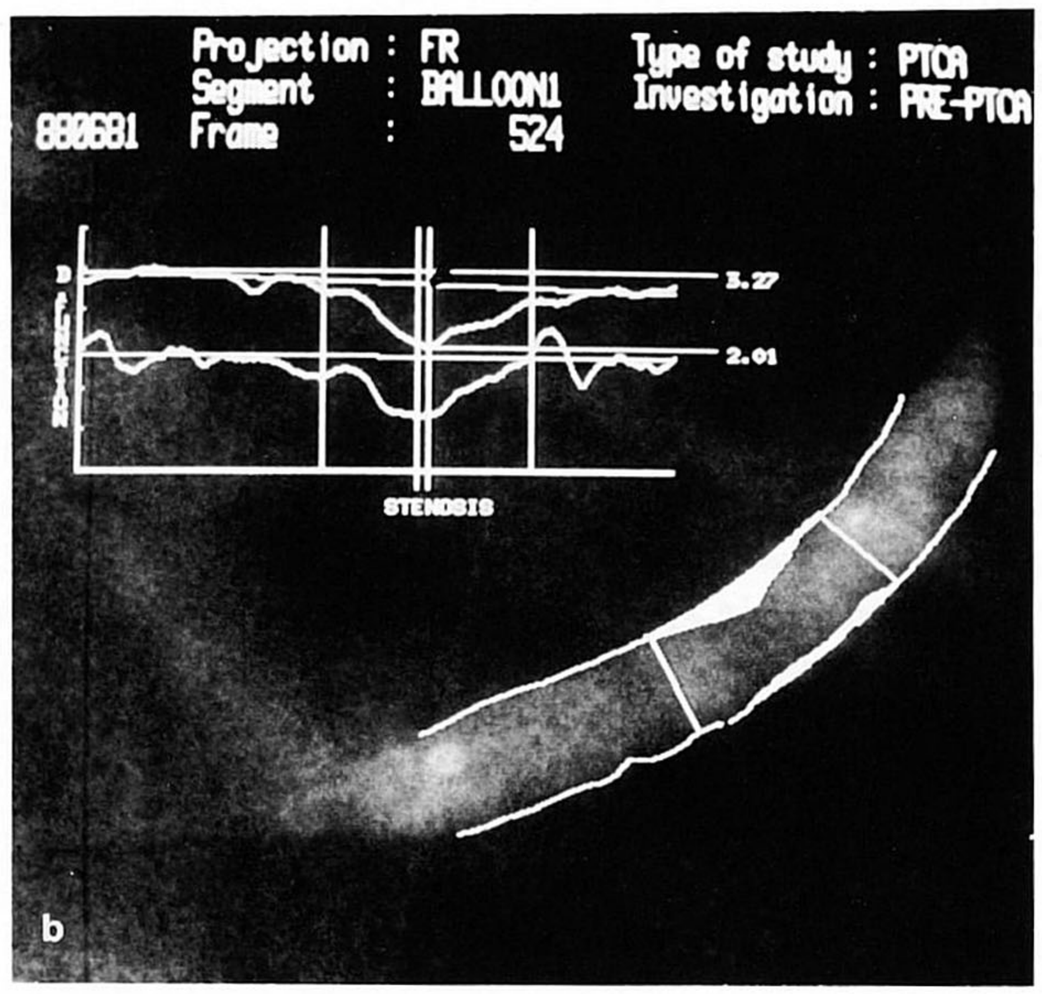
Edge Detection

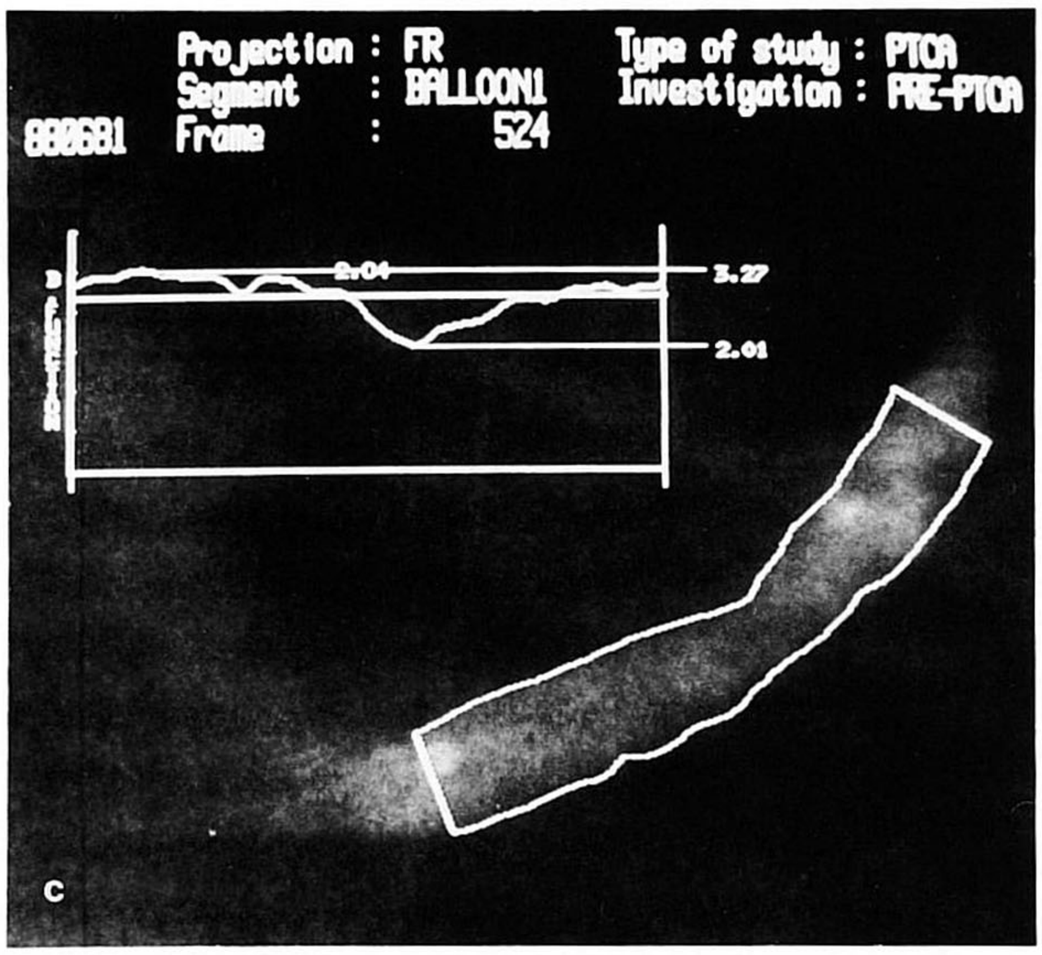
Any area sized 6.9 × 6.9 mm in a select cine-frame (overall dimensions 18 × 24 mm) encompassing the desired arterial segment was digitized by a high-resolution CCD camera with a resolution of 512 × 512 pixels and 8 bits of gray level. Vessel and balloon contours are determined automatically based on the weighted sum of the first and second derivative functions applied to the digitized brightness information along scanlines perpendicular to the local centerline directions of an arterial segment or inflated balloon. A computer-derived estimation of the original arterial or inflated balloon diameter at the site of obstruction is used to define the interpolated reference diameter. This technique is based on a computer-derived estimation of the original diameter values over the analyzed region (assuming there was no disease present) according to the diameter function. The absolute minimal values as well as the reference diameter are measured by the computer, which uses the known contrast-empty guiding catheter diameter as scaling device. To achieve maximal vasodilatation, either nitroglycerin or isosorbide dinitrate was given intracoronary for each coronary artery involved pre-PTCA and post-PTCA [7]. All contour positions of the catheters, the arterial segments, and the inflated balloon were corrected for pincushion distortion introduced by the individual image intensifiers.

Densitometric Analysis

Densitometry is based on the approximate linear relation that exists between the optical density of a contrast-enhanced lumen and the absolute dimensions of the arterial segment. Constitution of the relation between the path length of the x-rays through the artery or balloon and the brightness values requires a detailed analysis of the complete x-ray/cine/video chain, including the film development process [12,13,27]. For the first part of the chain, from the x-ray tube to the output of the image intensifier, we use Lambert Beer's law for the x-ray absorption and apply certain models for the x-ray source and the image intensifier. From the output of the image intensifier up to the brightness values in the digital image, we use a linear transfer function. The cross-sectional area of a vessel or balloon is then obtained as follows. The contours of a selected arterial segment or balloon (in a non-foreshortening view) are detected by automated edge detection as described above. On each scanline perpendicular to the local centerline direction of the vessel, a profile of brightness values is measured. This profile is transformed into an absorption profile by means of a simple logarithmic transfer function. The background contribution is estimated by computing the linear regression line through the background points directly left and right of the detected contours. Subtraction of this background portion from the absorption profile within the arterial contours yields the net cross-sectional absorption profile. Integration of this function gives a measure for the cross-sectional area at the particular scanline. By repeating this procedure for all scanlines, the cross-sectional area function is obtained. A reference densitometric area is obtained following the same principles as described above for the diameter measure-







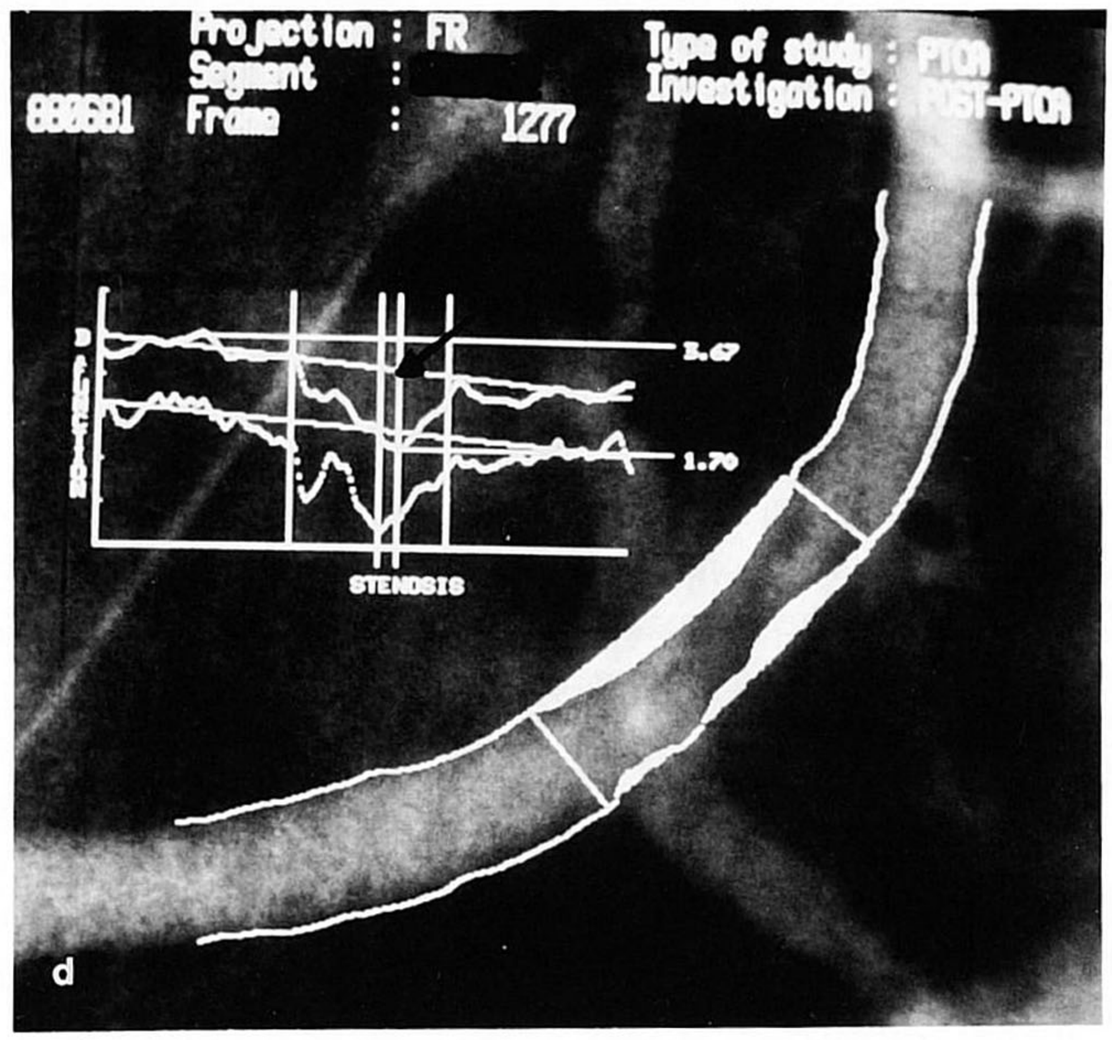


Fig. 1. Single frame angiogram of a mid portion of a circumflex artery. Superimposed on the video image are the diameter function curve (measured by edge detection [upper curve]) and the area function curve (measured by videodensitometry [lower curve]) of the severity of the obstruction before and after balloon dilatation (a,d) as well as of the balloon during maximal inflation (b,c). The interpolated reference diameter line is computed from the contours proximal and distal of the lesion. The reference diameter value is taken at the point coincident with the point of maximal narrowing (white arrow). The white areas are a measure for the "atherosclerotic plaque." b and c show the inflated balloon with an inflation pressure of 12 atm. The computer measured a minimal balloon diameter of 2.01 mm, a mean diameter over the entire length of the balloon of 2.84, a maximal diameter of 3.27, and a reference diameter of 2.99 mm (value not shown in figure). The nominal size of this balloon was 3.25 mm and was inflated at a maximum pressure of 12 atmospheres. These figures clearly show the non-uniform inflation process.

ments. It is clear that homogeneous mixing of the contrast agent and the blood must be assumed for the measurements to be correct. The complete procedure has been evaluated with cinefilms of Plexiglass^{R} of coronary obstructions [12,27].

Definitions of Quantitative Derived Morphologic Parameters

The area (mm^2) between the actual and reconstructed contours at the obstruction site is a measure of the amount of *atherosclerotic plaque* [12,28]. The *length of*

TABLE I. Quantitative Analysis of 505 Dilated Coronary Lesions and Inflated Balloons

	Pre-PTCA	Post-PTCA	*p* value
	Lesion		
Edge detection			
Minimal diameter (mm)	1.09 ± 0.31	1.83 ± 0.40	0.001
Reference diameter (mm)	2.70 ± 0.55	2.75 ± 0.51	0.001
Length lesion (mm)	6.5 ± 2.5	6.1 ± 2.6	0.001
Plaque area (mm^2)	7.09 ± 3.79	4.38 ± 3.32	0.001
Symmetry value	0.40 ± 0.24	0.35 ± 0.21	0.001
Curvature (units)	21.6 ± 10.9	20.4 ± 11.2	NS
Videodensitometry			
Minimal area (mm^2)	0.81 ± 0.79	2.63 ± 1.34	0.001
Reference area (mm^2)	5.98 ± 2.19	6.13 ± 2.33	0.001
	Balloon		
Edge detection		Videodensitometry	
Minimal diameter (mm)	2.37 ± 0.41	Minimal area (mm^2)	4.39 ± 1.61
Mean diameter (mm)	2.64 ± 0.40		
Maximal diameter (mm)	2.96 ± 0.44		
Reference diameter (mm)	2.75 ± 0.41	Reference area (mm^2)	6.09 ± 1.82
Nominal size (mm)	2.94 ± 0.39		

NS = Not significant.

the obstruction (mm) is determined from the diameter function on the basis of curvature analysis. *Symmetry* is defined as the coefficient of the left and right hand distance between the reconstructed interpolated reference diameter and actual vessel contours at the site of obstruction. In this equation the largest distance between actual and reconstructed contours becomes the denominator. A symmetrical location of the lesion has a value of 1 and a severely eccentric located lesion has a value of 0. To assess the extent of coronary bending, the *curvature* value at the obstruction site is computed as the average value of all the individual curvature values along the centerline of the coronary segment, with the curvature defined by the rate of change of the angle through which the tangent to a curve turns in moving along the curve and which for a circle is equal to the reciprocal of the radius.

Assessment of Stretch, Elastic Recoil, and Balloon-Artery Ratio

Stretch was defined as the ratio between the inflated balloon diameter (mm) minus the minimal luminal diameter (MLD) of the vessel pre-PTCA and the reference diameter (RD) (mm) of the dilated segment, and this represents the maximum diameter of the vessel at the time of balloon inflation:

$$\frac{\text{balloon diameter} - \text{MLD pre-PTCA}}{\text{RD pre-PTCA}}.$$

As previously published [12,13] *elastic recoil* of the stenosis is defined as the ratio between the balloon diameter (mm) minus the MLD post-PTCA (mm) and the reference diameter of the dilated segment and this represents the early loss in diameter immediately following balloon inflation:

$$\frac{\text{balloon diameter} - \text{MLD post-PTCA}}{\text{RD pre-PTCA}}.$$

Balloon-artery ratio was defined as the ratio between the balloon diameter and the reference diameter pre-PTCA of the dilated segment and attempts to describe the extent of balloon under or over sizing of the normal segment of the vessel:

$$\frac{\text{balloon diameter}}{\text{RD pre-PTCA}}.$$

Assessment of stretch, elastic recoil and balloon-artery ratio were derived from videodensitometry by substituting diameter measurements with densitometrically measured area measurements.

Statistical Analysis

All continuous variables were expressed as mean values ± standard deviation (SD) (Tables I,II) and a *t* test was applied to these variables (Table I). A value of <0.05 was considered statistically significant.

TABLE II. Variation in the Extent of Stretch, Elastic Recoil, and Balloon Artery Ratio in 505 Dilated Lesions

	Stretch	Elastic recoil	BAR
Edge detection			
Minimal balloon diameter (mm)	0.49 ± 0.18	0.21 ± 0.15	0.90 ± 0.17
Mean balloon diameter (mm)	0.59 ± 0.18	0.31 ± 0.15	1.00 ± 0.17
Reference diameter of balloon (mm)	0.63 ± 0.18	0.35 ± 0.16	1.04 ± 0.18
Maximal balloon diameter (mm)	0.71 ± 0.20	0.43 ± 0.18	1.12 ± 0.20
Nominal size of balloon (mm)	0.71 ± 0.21	0.43 ± 0.18	1.12 ± 0.20
Videodensitometry			
Minimal area of balloon (mm^2)	0.67 ± 0.37	0.34 ± 0.32	0.81 ± 0.36
Reference area of balloon (mm^2)	0.98 ± 0.42	0.65 ± 0.36	1.12 ± 0.41
Nominal area of balloon (mm^2)	1.16 ± 0.54	0.82 ± 0.45	1.29 ± 0.51

BAR = Balloon-artery ratio.

To measure the strength of the relation between the nominal size and the measured balloon diameter, the product-moment correlation coefficient (r) and its 95% confidence intervals (CI) were calculated. The agreement between the two measures was assessed by determining the mean and the SD of the between-method difference as suggested by Bland and Altman [29]. This was done by computing the sum of the individual differences between the two measures to determine the mean difference and the SD. The same statistical method was applied to assess the relationship between the minimal cross-sectional area derived from edge detection and videodensitometry as well as of the inflated balloon.

To assess the relationship between several angiographic morphological variables (area plaque, curvature, length of the lesion, symmetry) and recoil, a univariate analysis was performed. To avoid arbitrary subdivision of data, cut off criteria for continuous variables were derived by dividing the data in three groups so that each group contained about one-third of the population. The group with the highest amount of recoil was then compared with the two other groups [30]. This method of subdivision has the advantage of being consistent for all variables and thus avoids any bias in selection of subgroups which might be undertaken to emphasize a particular point (Table III).

Analysis was carried out with a commercial statistical package (BMDP Statistical Software 1990).

RESULTS

Quantitative angiographic lesion characteristics of the 505 lesions dilated and of the balloon at highest inflation pressure used, are shown in Table I.

Lesion

The minimal luminal diameter increased from 1.09 ± 0.31 mm to 1.83 ± 0.40 mm after PTCA with an increase in minimal cross-sectional area from 0.81 ± 0.79 mm^2 to 2.63 ± 1.34 mm^2 ($p < 0.001$). There was a significant change in "interpolated" reference diameter after PTCA: 2.70 ± 0.55 mm pre-PTCA and 2.75 ± 0.51 mm post-PTCA, and in reference area: 5.98 ± 2.19 mm^2 pre-PTCA and 6.13 ± 2.33 mm^2 post-PTCA ($p < 0.001$).

Balloon

The average length of the balloon analyzed was 16.2 ± 3.7 mm; the tapered proximal and the distal part of the balloon were not included in the analysis (Fig. 1). The average inflation pressure used was 8.3 ± 2.6 atm, the number of inflations varied between 1 and 17 (mean 3.1 times), and the average inflation time was 255 ± 217 sec. As shown from Table I the balloon is not uniformly inflated over its entire length at the highest pressure used. Quantitative analysis showed a mean difference of 0.59 ± 0.26 mm between the maximal and minimal balloon diameter in case of edge detection and 1.70 ± 0.90 mm^2 between the reference area and minimal area by videodensitometry.

The manufacturer's size of the balloon used was 2.94 ± 0.39 mm (range 2.0 to 4.2 mm). The mean difference (± SD) in diameter (and the corresponding r and 95% CI) between the nominal diameter of the balloon and its in vivo measured diameter using *edge detection* were

0.66 ± 0.32 for the minimal balloon diameter (r = 0.67; 95% CI = 0.62 to 0.72),
0.30 ± 0.29 for the mean balloon diameter (r = 0.73; 95% CI = 0.69 to 0.77),
0.19 ± 0.31 for the reference balloon diameter (r = 0.71; 95% CI = 0.66 to 0.75),
−0.02 ± 0.33 for the maximal balloon diameter (r = 0.68; 95% CI = 0.63 to 0.72) (Fig. 2A–D).

Although the nominal size of the balloon during inflation is reached at the maximal balloon diameter, it appears

TABLE III. Influence of the Balloon Diameter or Area Used in the Univariate Analysis of Elastic Recoil

	Symmetry			Curvature			Area plaque			Length lesion		
Balloon	< 0.24 # 164	> 0.24 # 341	*p*	< 16 # 171	> 16 #334	*p*	< 5.1 # 170	> 5.1 # 335	*p*	< 5.2 # 168	> 5.2 # 337	*p*
Edge detection												
Minimal diameter	0.23	0.20	0.08	0.23	0.20	0.03	0.22	0.20	0.14	0.22	0.21	0.56
Mean diameter	0.33	0.30	0.15	0.33	0.30	0.03	0.34	0.30	0.001	0.32	0.31	0.26
Maximal diameter	0.45	0.43	0.25	0.45	0.42	0.07	0.47	0.42	0.001	0.45	0.43	0.21
Reference diameter	0.37	0.35	0.15	0.38	0.34	0.02	0.38	0.34	0.001	0.37	0.35	0.25
Nominal size	0.44	0.43	0.34	0.44	0.42	0.24	0.48	0.41	0.001	0.45	0.42	0.10
Videodensitometry												
Obstruction area	0.37	0.32	0.08	0.39	0.31	0.02	0.42	0.30	0.001	0.35	0.33	0.50
Reference area	0.69	0.63	0.11	0.72	0.61	0.001	0.77	0.59	0.001	0.70	0.62	0.04
Nominal area	0.85	0.81	0.40	0.88	0.79	0.05	1.01	0.72	0.001	0.89	0.79	0.02

that the balloon is not inflated at the theoretical diameter along its entire length.

The mean differences (± SD) in area (and the corresponding r and 95% CI), calculated using the cross-sectional area of the balloon, derived from the nominal size assuming a circular model of the balloon and from *videodensitometry* measurements, were

2.53 ± 1.56 for the minimal balloon area
(r = 0.59; 95% CI = 0.53 to 0.64),
0.83 ± 1.42 for the reference balloon area
(r = 0.70; 95% CI = 0.65 to 0.74) (Fig. 2E,F).

Stretch

Stretch measurement derived from edge detection varied between 0.49 ± 0.18—when the minimal value of the balloon diameter was chosen—and 0.71 ± 0.21 if the nominal size of the balloon or the maximal value of the balloon diameter was used. When videodensitometry is applied, stretch measurement varied between 0.67 ± 0.37—when the minimal value of the balloon area was chosen—and 1.16 ± 0.54 if the nominal area of the balloon (derived from the nominal balloon size) was used (Table II).

Elastic Recoil

Elastic recoil measurement derived from edge detection varied between 0.21 ± 0.15—when the minimal value of the balloon diameter was chosen—and 0.44 ± 0.18 if the maximal value of the balloon diameter was used. With videodensitometry, elastic recoil measurement varied between 0.34 ± 0.32 using the minimal value of the balloon area and 0.82 ± 0.45 using the nominal area of the balloon (derived from the nominal size) (Table II).

Table III shows the influence of the selected balloon diameter on the univariate analysis of elastic recoil. For each morphologic parameter, different levels of significance were observed. For instance, the degree of curvature was significantly related to the recoil phenomenon when the value of the minimal, mean, or reference balloon diameter was selected. However, the relation is no longer significant if the maximal value of the balloon diameter or the nominal balloon size was considered. The amount of area plaque is significantly related to the recoil phenomenon with less plaque giving more elastic recoil. This is of significance for all selected balloon diameters or areas except when the minimal value of the balloon diameter was selected.

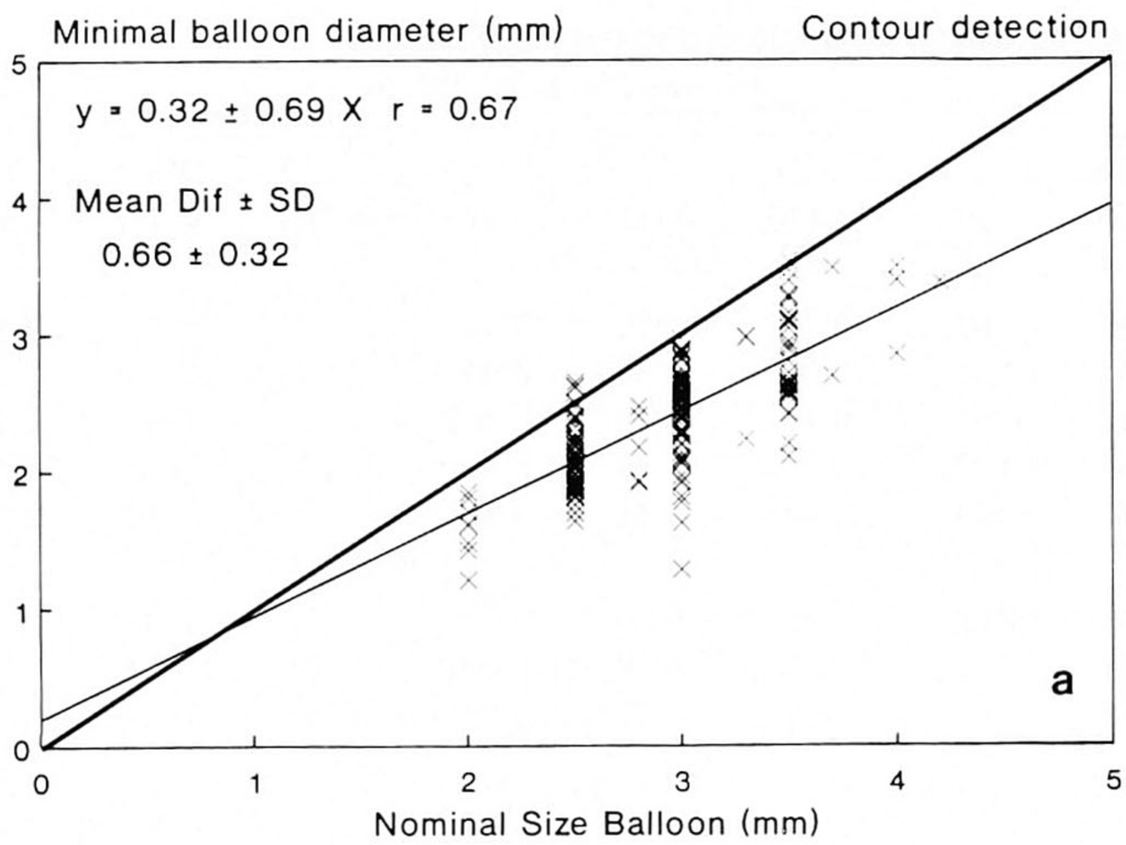
Balloon-Artery Ratio

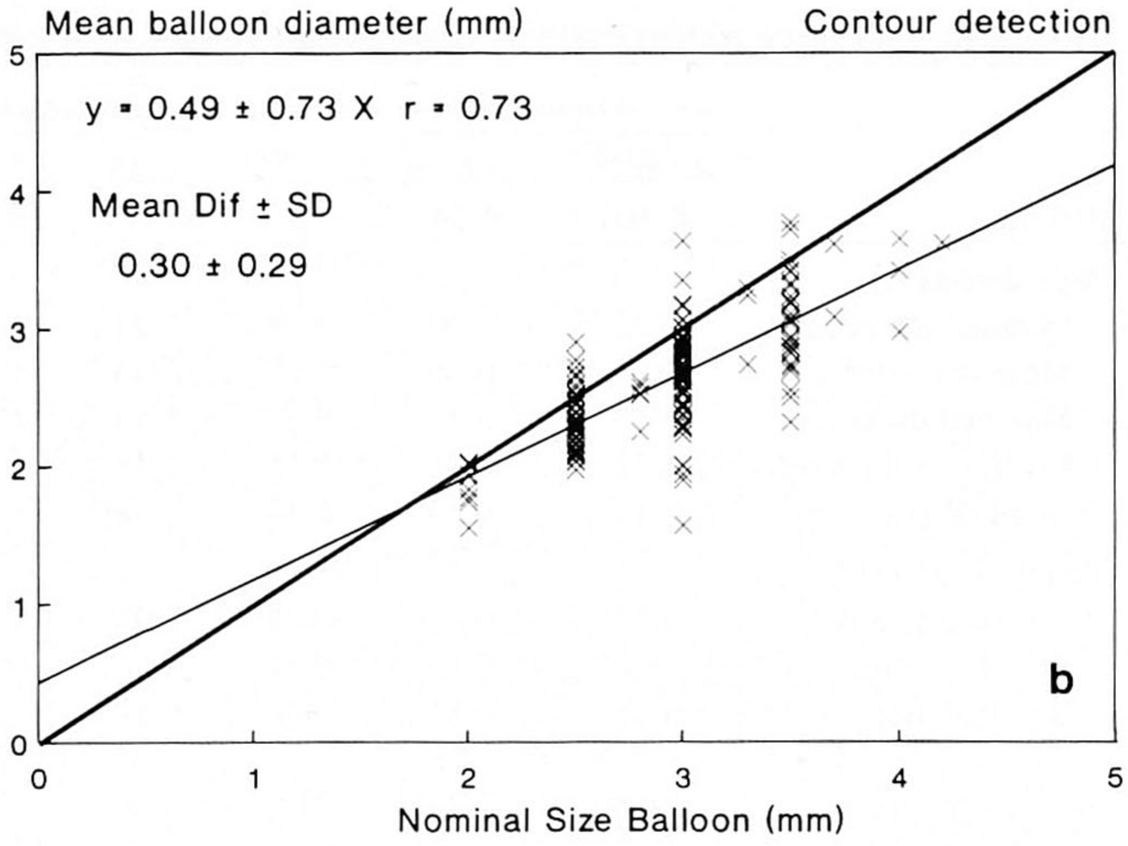
Balloon-artery ratio derived from edge detection varied between 0.90 ± 0.17 when the minimal value of the balloon diameter was chosen, and 1.13 ± 0.20 with the maximal value. With videodensitometry, the balloon-artery ratio varied between 0.81 ± 0.36 (with the minimal value of the balloon area) and 1.29 ± 0.51 when the nominal area of the balloon was selected (Fig. 3).

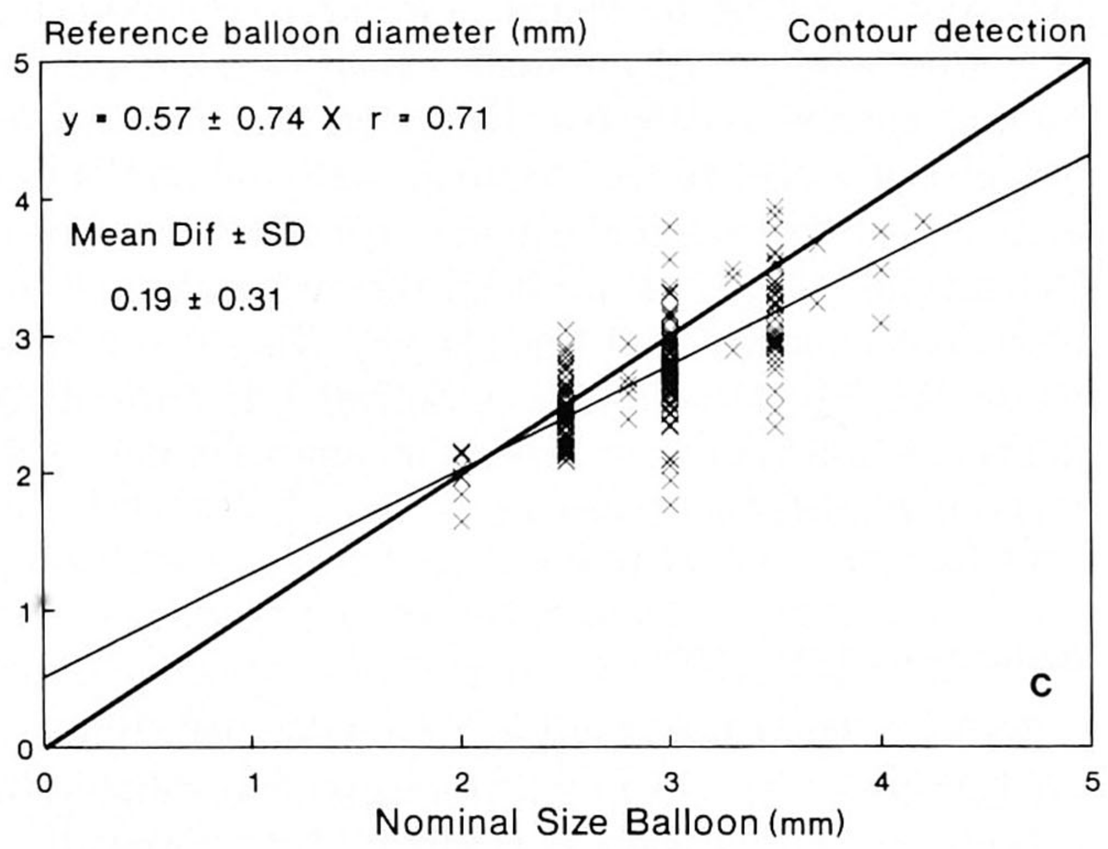
Comparison Between Edge Detection and Videodensitometry in the Assessment of Lesion Severity Pre- and Post-PTCA, of the Inflated Balloon, and of Stretch and Elastic Recoil

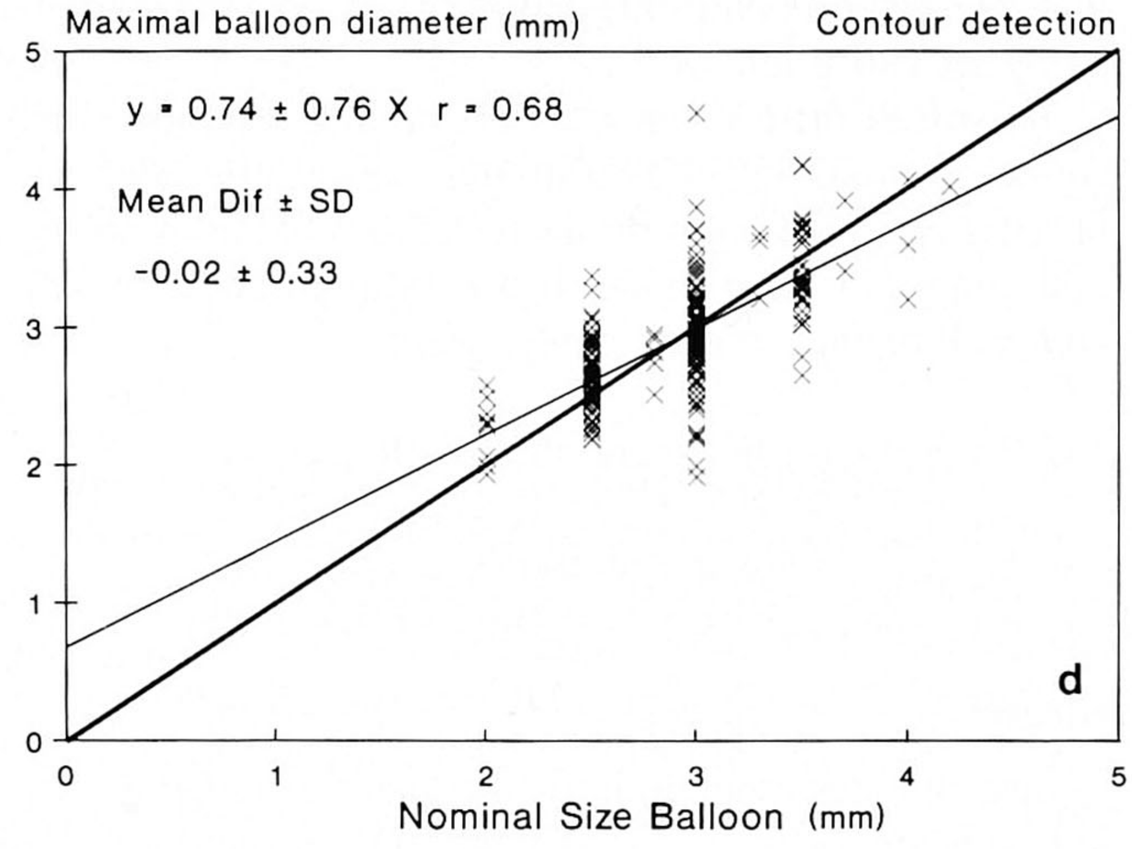
Lesion and balloon. The mean differences (± SD) between the minimal luminal cross-sectional area pre-TPCA, post-PTCA, and of the balloon derived from edge detection (assuming a circular cross-section) and measured by videodensitometry are 0.11 ± 0.50 mm^2, 0.11 ± 1.04 mm^2, and 0.16 ± 0.89 mm^2, respectively. (Fig. 4).

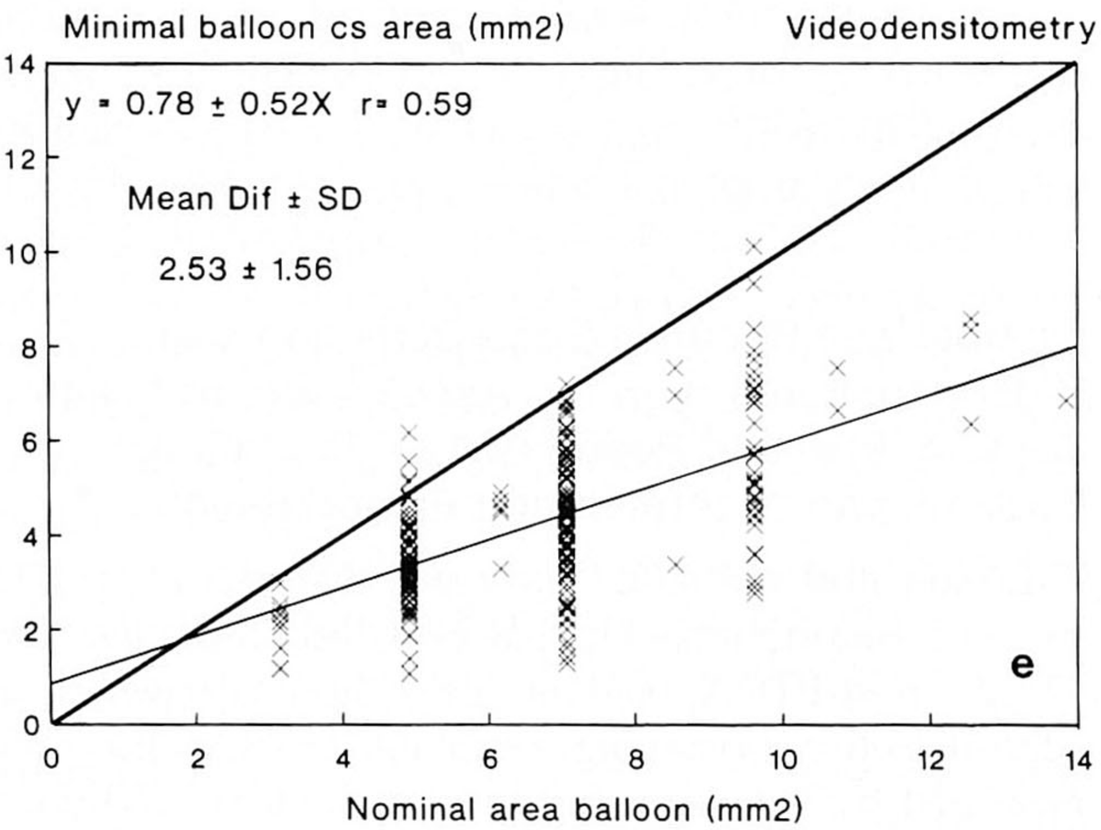
Stretch and recoil. Figure 5 shows the relationship between stretch and elastic recoil assessed by edge detection and videodensitometry using the minimal luminal diameter or area of the balloon. The mean difference (± SD) between the two measurements are respectively 0.00 ± 0.19 for stretch and 0.00 ± 0.24 for elastic recoil.











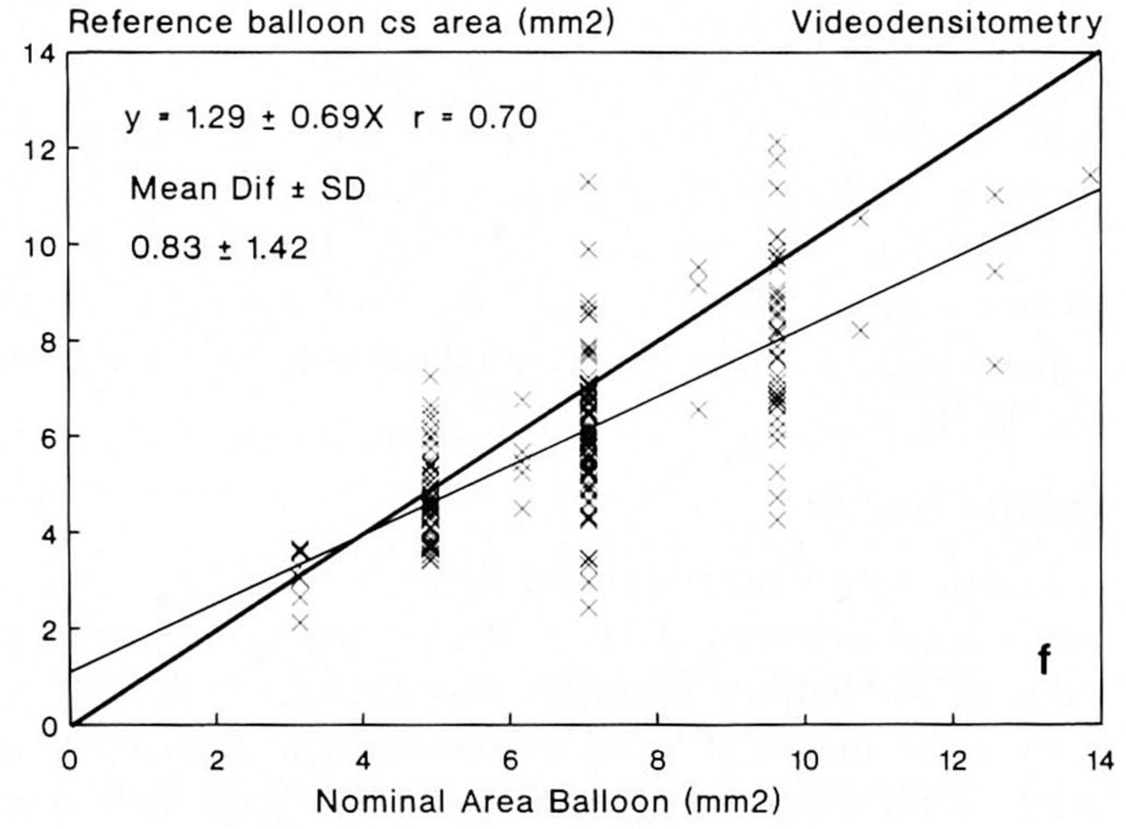


Fig. 2. Four different balloon diameters measured by edge detection versus the nominal size of the balloon (a–d) and two different balloon area's measured by videodensitometry versus the nominal area of the balloon (e,f). Mean Dif ± SD = Mean difference and standard deviation between the measured balloon diameter (area) and the nominal size (area) of the balloon. r = correlation coefficient with regression line.

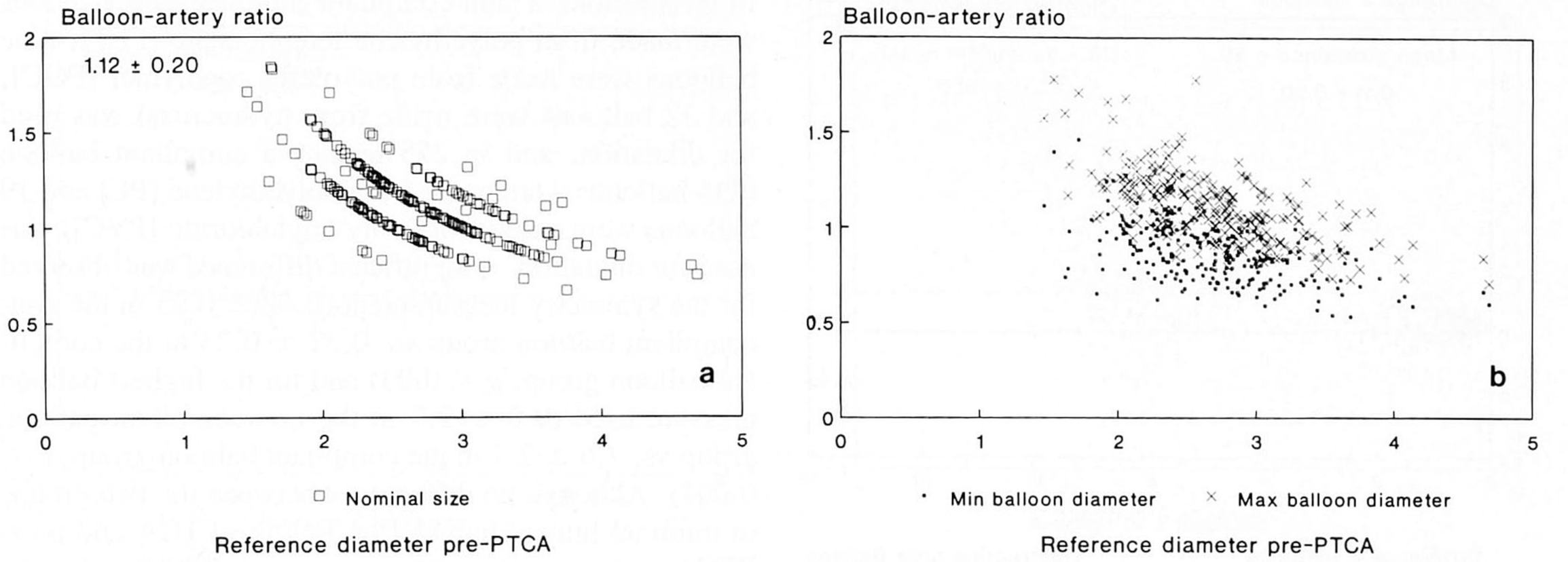


Fig. 3. The balloon-artery ratio vs. the reference diameter pre-PTCA. Depending on whether the nominal size (a) or the minimal or the maximal balloon diameter (b) is used, a single balloon inflation may be judged to be under sized (ratio $<$ 1) or over sized (ratio $>$ 1). Over sizing occurs more frequently in small vessels and under sizing more frequently in large ones.

DISCUSSION

This study showed that the balloon is not uniformly inflated at the highest pressure used. A maximal difference of 0.59 ± 0.26 mm in balloon diameter was measured at an average inflation pressure of 8.3 atm. Histologic studies have shown that the vast majority of atherosclerotic plaques in human coronary arteries are composed of dense fibrocollagenous tissue with varying amounts of calcific deposits and smaller amounts of intracellular and extracellular lipid (''hard plaques'') [31]. Certain parts of plaques may restrict complete balloon expansion, which explains the pattern of non-uniformity. It has been the common clinical experience of many operators that some lesions will not yield even at inflation pressure up to 20 atm. Recently intravascular ultrasound images have confirmed this non-uniform inflation pattern during coronary angioplasty (personal communication, Dr. Jeffrey Isner).

Edge Detection and Videodensitometry

Ideally in the assessment of stretch and elastic recoil, the measurement of interest is the precise relationship between the cross-sectional area of the vessel and the balloon at the site of the obstruction. It might be assumed that at each stage of the procedure, the luminal area of the vessel at the stenotic site is not circular so that the geometric evaluation (assuming a circular model) of stretch and the recoil phenomenon might be misleading particularly after the disruptive effect of balloon angioplasty. As earlier reported, the use of edge detection may be limited in the analysis of dilated lesions immediately following angioplasty [9,13] because acute tears and dissections distort the anatomy. From a theoretical point of view, a videodensitometric approach seems to be the ultimate solution in measuring the vessel and balloon cross-sectional area in a single angiographic view. Although densitometry is independent of geometric shape, this technique seems to be more sensitive than edge detection to densitometric nonlinearities (x-ray scatter, image intensifier veiling glare, and beam hardening), oblique projection of the artery, and overlap with other structures, and its application is limited in the presence of branch vessels that may cause errors in the background correction technique and in situations where the x-ray beam is not perpendicular to the long axis of the vessel [16].

In the present study it was felt that the videodensitometric approach was used in relatively optimal condition since the inflated balloon was filmed in the least foreshortened view (for safety reasons), thereby avoiding large errors due to potential changes in background scatter and veiling glare. During inflation of the balloon, the surrounding coronary vessels were not opacified, thus minimizing the problems related to the background correction. However, the analysis of the lesion remains subject to the well known pitfalls (mentioned in the previous paragraph) encountered with the videodensitometric technique. Despite the well known technical limitations, the assessment of stretch and elastic recoil by videodensitometry did not significantly differ from the assessment derived from edge detection and both techniques might be used in the future on-line in the catheterization laboratory during coronary angioplasty.

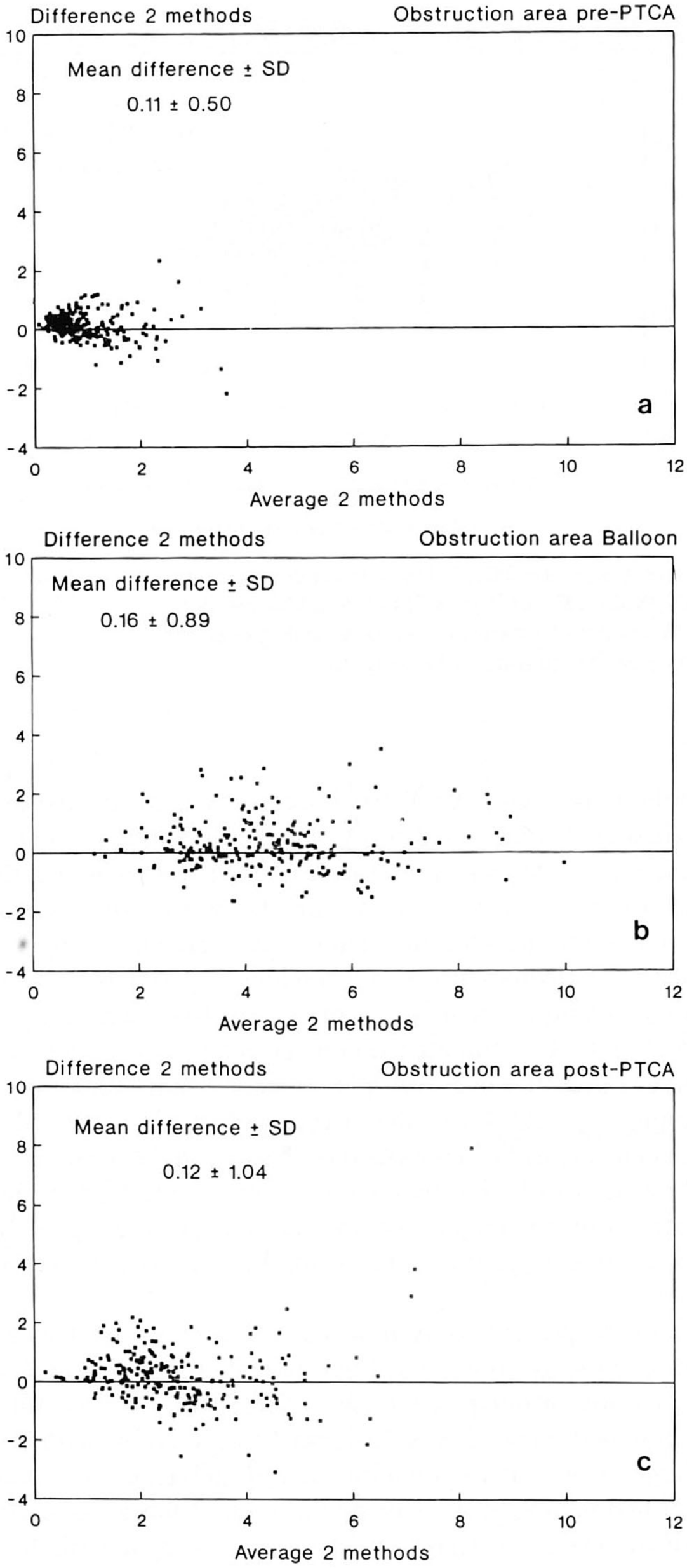


Fig. 4. The mean difference (± SD) between the mimimal luminal cross sectional area pre-PTCA (a), during balloon inflation (b), and post-PTCA (c) derived from edge detection and videodensitometry.

Compliant Vs. Non-Compliant Balloons

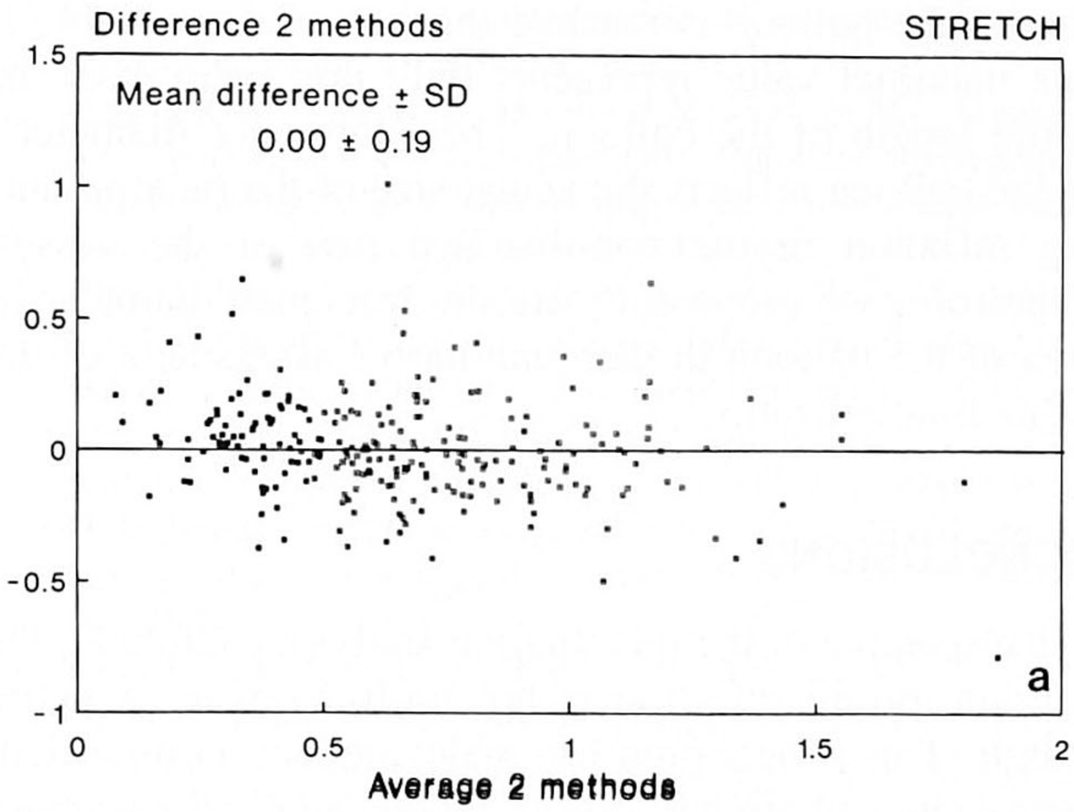
In this study, the choice to use a compliant or non-compliant balloon during PTCA was left to the operator. In 250 lesions a non-compliant balloon (209 balloons were made from polyethylene terephthalate [PET], nine balloons were made from polyolefin copolymer [POC], and 32 balloons were made from hydracross) was used for dilatation, and in 255 lesions a compliant balloon (236 balloons were made from polyethylene [PE] and 19 balloons were made from polyvinylchloride [PVC]) was used for dilatation. A significant difference was observed for the symmetry measurement (0.42 ± 0.25 in the non-compliant balloon group vs. 0.37 ± 0.23 in the compliant balloon group, $p < 0.03$) and for the highest balloon pressure used (9.0 ± 2.7 in the non-compliant balloon group vs. 7.6 ± 2.2 in the compliant balloon group, $p < 0.001$). Although no differences between the two groups in minimal lumen diameter or area pre-PTCA and post-PTCA, reference diameter or area pre-PTCA and post-PTCA, diameter stenosis or area stenosis pre-PTCA, nominal balloon size, calculated stretch, elastic recoil, and the balloon-artery ratio was observed, there was a significant difference in post-PTCA diameter stenosis—with a better result in the group where lesions were dilated with a compliant balloon type (diameter stenosis of 32% vs. 34% in the non-compliant balloon group). It is possible that this difference is caused by the type of lesions dilated (different symmetry) or due to the maximal balloon pressure used. A comparative study is warranted to investigate if this difference in post-PTCA result between the two groups is significant or that it reflects differences in selection.

Which Measured Balloon Diameter Should Be Used in the Quantitative Assessment of Stretch, Elastic Recoil, and Balloon-Artery Ratio?

It is clear from our study that the nominal size of the balloon listed by the manufacturer should not be used in the assessment of stretch and elastic recoil of the stenotic lesion or in the assessment of the balloon-artery ratio because the nominal size is not reached at the stenotic site even at an average pressure of 8.3 atm.

Stretch

To determine the actual amount of stretch at the obstruction, we propose to use the minimal diameter or area in the balloon during inflation as this persistent encroachment of the balloon during inflation presumably localizes the non-distensible part of the stenosis that restricts the dilatation. Even more accurate would be a superimposition of the two diameter functions of the dilated vessel and inflated balloon to continuously assess stretch over the entire length of the dilated lesion (Fig. 6).



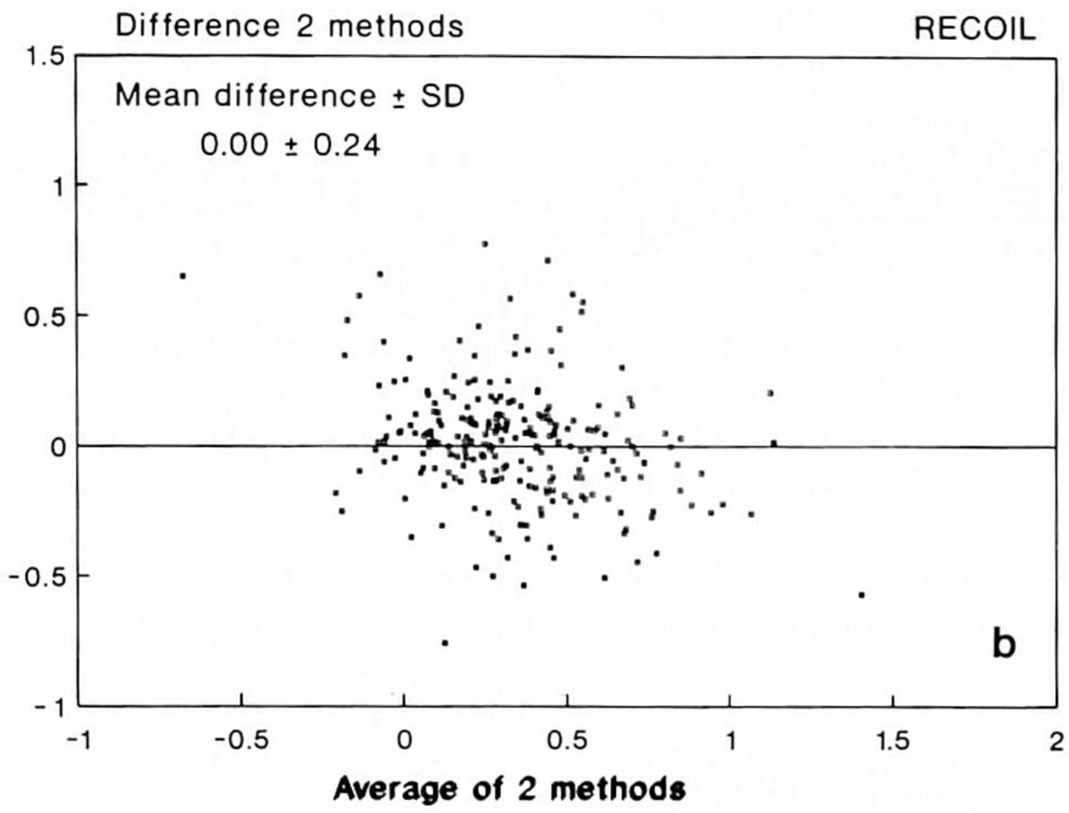


Fig. 5. a: The relation between stretch using edge detection and videodensitometry (the minimal luminal diameter or area of the balloon). b: The relation between elastic recoil using edge detection and videodensitometry (the minimal luminal diameter or area of the balloon).

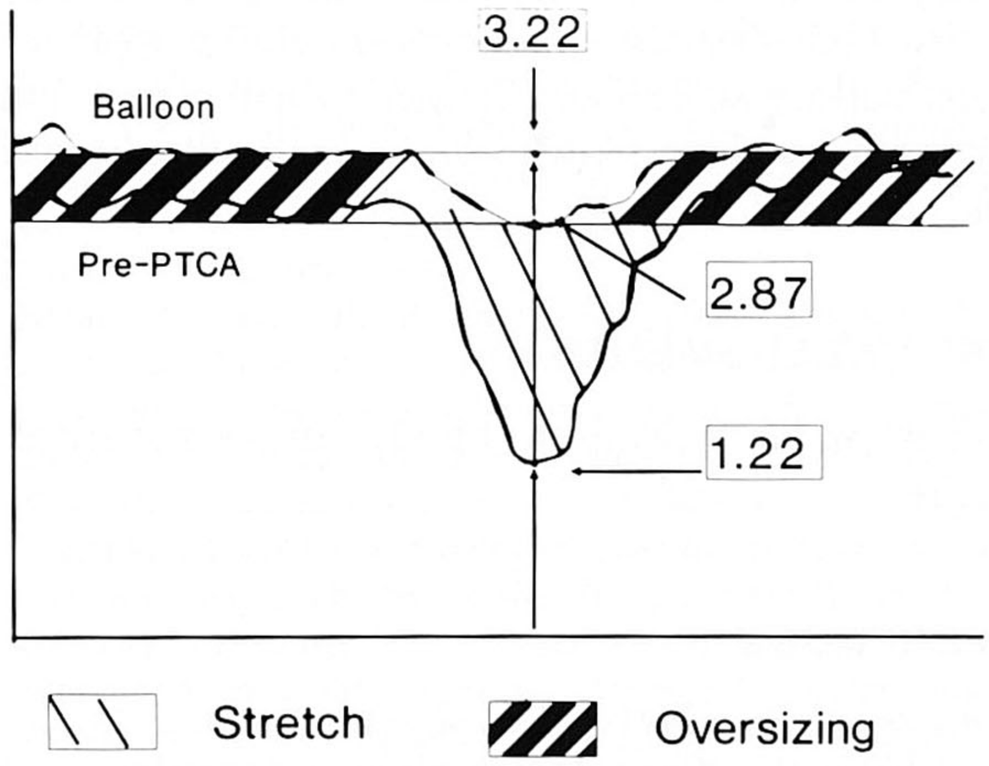


Fig. 6. In this example the minimal luminal diameter of the lesion pre-PTCA and during balloon inflation are 1.22 mm and 2.87 mm respectively. The interpolated reference diameter for the lesion is 2.87 mm and for the balloon 3.22 mm. The nominal size of the balloon is 3.5 mm. Theoretically the maximal gain is 3.50 − 1.22 = 2.27 mm. However, due to the atherosclerotic plaque in the vessel wall, complete balloon expansion was not achieved. Stretch of the lesion was (2.87 − 1.22) / 2.87 = 0.57. The upper line represents the diameter function curve of the balloon over the entire length of the balloon at maximum inflation pressure. The lower line represents the diameter curve pre-PTCA. The two interpolated reference diameter lines are also shown (see arrows). The difference between these two lines represents the balloon-artery ratio (/ / /). It is clear that in this example oversizing took place: the interpolated reference diameter of the balloon is 3.22 mm and of the stenosis 2.87 mm; this results in a balloon-artery ratio of 1.12. In this case, the minimal diameter of the balloon and the lesion are localized at the exact same spot; however, this is not always the case.

Elastic Recoil

Recently Monson et al. [4] studied in 27 patients the angiographic patterns of balloon inflation during PTCA. Videodensitometry was used to measure the diameter of the inflated balloon and of the lesion pre-PTCA and post-PTCA. They defined recoil as the ratio between the balloon diameter at 6 atm and the coronary diameter after angioplasty. They found that the nominal size of the balloon was almost never reached over the entire length of the balloon. Our data is in agreement with their observation (Table I).

Any analysis of factors affecting the recoil phenomenon will be greatly influenced by the selection of the value of the balloon diameter or area (minimal, mean, maximal, reference, or nominal) used for the calculation of the elastic recoil. Our group earlier reported that more elastic recoil was seen in asymmetric lesions (<0.37), lesions located in less angulated parts of the artery (<12.5 units), and in lesions with a small plaque content (<4.7 mm^2) [12]. In that latter study, the mean diameter (derived over the entire length) of the balloon was used. Table III shows the influence of the selected balloon diameter or area on the univariate analysis of factors affecting elastic recoil. From this table it is clear that small area plaque (<5.08 mm^2) and lesions located in less angulated parts of the vessel (curvature < 16.3 units) are significantly or not significantly affecting the recoil phenomenon of the lesion depending on the balloon diameter chosen for analysis.

To accurately assess the extent of elastic recoil at the site of severest luminal narrowing we suggest use of the minimal value of the balloon diameter or area as this measurement presumably reflects the narrowing persisting at the site of the stenosis during dilatation. Even more accurate would be a superimposition of the two diameter functions of the dilated vessel and inflated balloon to continuously assess elastic recoil over the entire length of the dilated lesion (Fig. 7).

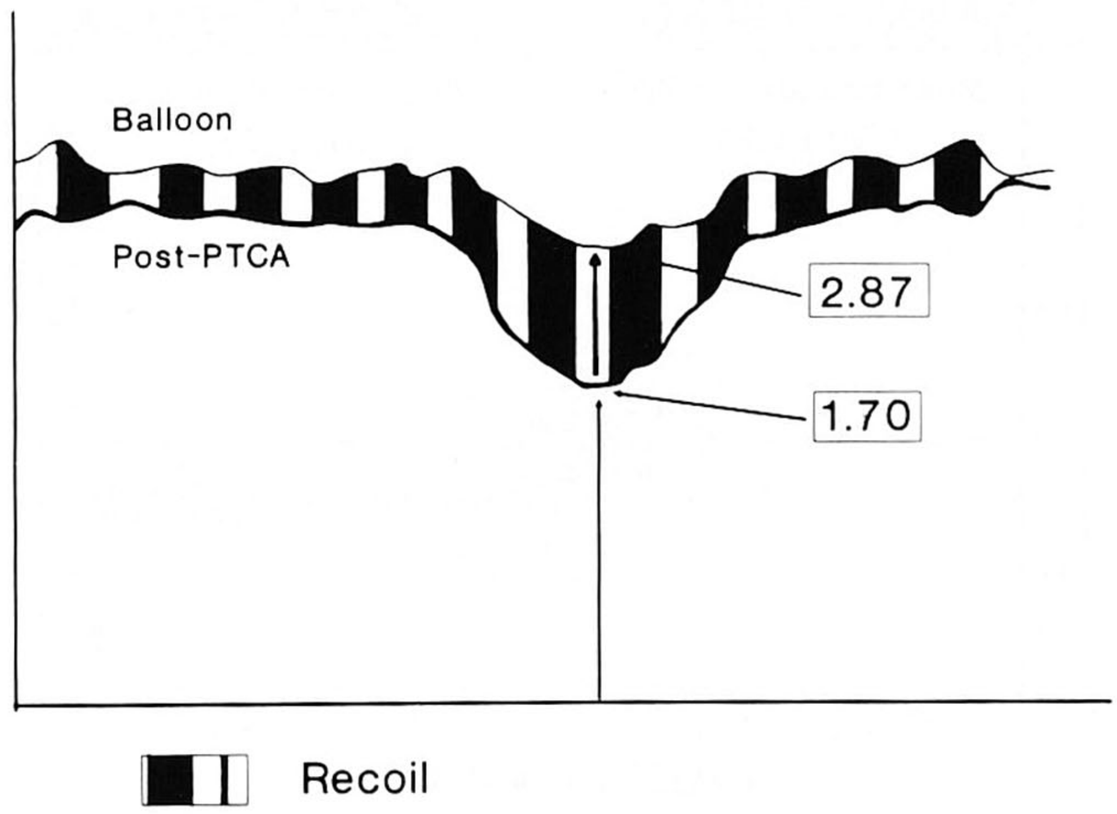


Fig. 7. The upper line represents the diameter function curve of the balloon; this shows what maximally was achieved during PTCA. The lower line represents the diameter function curve post-PTCA. //// = elastic recoil; represents what is lost in diameter immediately post-PTCA. Post-PTCA the minimal luminal diameter is 1.70 mm. Immediately post-PTCA (2.87 − 1.70) / 2.87 = 0.41 is lost due to elastic recoil. The ratio of elastic recoil is not necessarily at its maximum at the minimal obstruction site of the vessel.

Balloon-Artery Ratio

In the present study, the balloon-artery ratio derived from edge detection varied between 0.90 ± 0.17 (undersized) and 1.13 ± 0.20 (oversized) is selected (Fig. 3).

Roubin et al. [23] defined the balloon-artery ratio by estimating the so-called normal lumen of the coronary artery by direct visual comparison to the known diameter of the guiding catheter used. Then the patients were randomized to a (nominal) balloon size smaller or larger than this so-called normal lumen. They found more acute complications with a balloon size greater than the so-called normal lumen. Nichols et al. [24] compared the diameter of the inflated balloon to a normal artery (in most cases proximal of the stenosis (adjacent to the stenosis (user-defined). In this study, balloon sizes provided by the manufacturers were used. They concluded that the interventional cardiologist should approximate or slightly exceed the diameter of the normal arterial diameter in order to achieve optimal angiographic results with minimal dissections and minimal residual stenosis since oversized balloons (ratio > 1.3) caused a higher incidence of dissections.

Over- and under-sizing of the balloon with respect to the vessel dilated always refers to the non-diseased part of the vessel as over-sizing of the stenotic lesion itself always takes place (Fig. 6). So, in theory, the nominal size of the balloon and the non-diseased diameter pre-PTCA should be used for the balloon-artery ratio. However, the present data shows that although the nominal size of the balloon is reached during inflation (Table I) this maximal value represents only one point over the entire length of the balloon. The ''reference diameter'' of the balloon reflects the actual size of the balloon during inflation in the non-diseased part of the vessel. Therefore, we propose to use the reference diameter or area of the balloon in the quantitative assessment of the balloon-artery ratio.

CONCLUSIONS

Irrespective of the quantitative analysis technique, the balloon during inflation is not uniform over its entire length. This observation has major impact on the calculated values of stretch, elastic recoil, and balloon-artery ratio. As on-line quantification of the lesion before and during PTCA as well as of the inflated balloon is technical feasible during routine PTCA, our observation is of clinical significance and it could help to determine whether higher balloon pressures should be applied or a greater balloon size should be used to achieve an optimal short-term and long-term result of the angioplastied lesion.

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