

Original Article

Acute recoil of stents used for the relief of stenotic great vessels in the setting of congenital cardiac disease

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Abstract We implanted either large or medium Palmaz stents, or a Palmaz Corinthian stent, in various stenotic vessels, such as the pulmonary arteries, pulmonary veins, aorta, or superior caval vein. Using angiograms, we measured the diameter of the stenotic vessel before or after the implantation, the minimal diameter of the lumen, the minimal diameter of the largest fully expanded balloon used to expand the stent, and the diameter immediately after withdrawal of the balloon.

The minimal diameter of the fully expanded balloon, and the minimal diameter of the lumen subsequent to expansion, were 8.2 ± 2.4 , and 7.7 ± 2.3 mm, giving an absolute recoil of 0.5 ± 0.4 mm, and a proportional recoil of $7 \pm 4\%$. There was no significant difference in either the absolute or proportional recoil for any of the stents, or for any of the different stenotic vessels. The proportional recoil correlated linearly with the minimal diameter of the lumen prior to the procedure, and with the ratio of the stenosis to the balloon, while the diameter of the stenotic vessels, the minimal diameter of the largest fully expanded balloon, the proportional stenosis prior to the procedure, and the ratio of the balloon to the diameter of the stenotic vessel, had no significant correlation with proportional recoil. The proportional recoil exceeded more than one-tenth when the minimal diameter of the lumen prior to the dilation was less than 3 mm, or the ratio of the balloon to the stenosis was greater than 3.0.

An absolute recoil of around 1 mm is common when a large or medium Palmaz, or a Palmaz Corinthian stent, is implanted in great vessels. Balloons with a diameter of approximately one-tenth greater than that of the adjacent vessel may be needed if the minimal diameter of the lumen is small prior to the procedure.

Keywords: Congenital cardiac malformations; interventional cardiology

BALLOON EXPANDABLE STENTS ARE USEFUL devices for maintaining the caliber of the lumen in children with congenital or postoperative stenoses of the great vessels.^{1–6} The size of the balloon used to expand a stent is commonly chosen so that the diameter subsequent to inflation is 3 or 4 times the narrowest diameter of the stenosis, or equal to the diameter of the vessel adjacent to the site of narrowing, whichever is smaller.^{1,2,4–6} As has been reported for coronary arterial stents, however, acute recoil of the stent subsequent to inflation may cause suboptimal

dilation of the stenosis.^{7–10} As we currently choose a balloon with a diameter approximately 1 mm larger than the diameter of the vessel adjacent to the stenosis, we retrospectively studied the validity of this concept by measuring the acute recoil of stents used to dilate various stenotic lesions in the setting of congenital cardiac disease.

Subjects and methods

Population studied

We assembled angiograms, satisfactory for quantification, obtained after the dilation of 71 lesions in 50 patients successfully expanded with either a single medium or large Palmaz stent, or a Palmaz Corinthian stent, between June 1999 and May 2002. The age and body weight of the patients at the time of implantation

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ranged from 0.2 to 28 years, with a median of 7 years, and from 2.8 to 77.5 kg, with a median of 19.4 kg. The stenotic lesions obstructed the pulmonary arteries in 37 patients; the aorta in 13; the pulmonary veins in 10; the superior caval vein in 7; and miscellaneous lesions in the remaining 4, including the right ventricular outflow tract, a calcified valved pericardial roll, and a Blalock-Taussig shunt. We had implanted large Palmaz stents in the pulmonary trunk or right ventricular outflow tract, the branches of the pulmonary trunk, the aorta, and the superior caval vein. Medium stents had been used in the peripheral pulmonary arteries distal to their first branch, the pulmonary veins, and the Blalock-Taussig shunt. Palmaz Corinthian stents were implanted only in the pulmonary arteries or veins in the circumstances where rigid Palmaz stents were difficult to introduce because of acute angles or tortuous routes of access.

Implantation

Under general anesthesia, we implanted 48 large Palmaz stents, using the models P308, P188, or P128, 12 medium stents with a length of either 10, 15, 20, 29, or 39 mm, and 11 Palmaz-Corinthian stents of the patterns PQ154~157BLS, PQ185BJS, PQ296BLS, PQ297BLS, and PQ398BLS as described previously.¹⁻³ We made several minor modifications of our original approach. The original Palmaz stents were manually crimped on high pressure Cordis Power Flex or Opta Lp balloons. Previously, the balloon chosen to expand the stent had an inflated diameter that was 3 to 4 times the narrowest diameter of the stenosis, or equal to the size of the segment adjacent to the narrowing, whichever was smaller. Whenever possible in our current experience, however, we chose a balloon with a diameter approximately 1 mm larger than the diameter of the vessel adjacent to the stenosis. The long sheath covering the balloon was occasionally inserted as a single unit over an exchange wire, using femoral vascular access. Prior dilation was performed in 2 lesions in the pulmonary arteries, in 1 lesion in the aorta, and in 1 Blalock-Taussig shunt, when the long sheath could not be advanced through the lesion, or the initial dilation had proved ineffective. Palmaz Corinthian stents, which were pre-mounted on high pressure Cordis Opta LP or Jupiter balloons, were occasionally implanted without the use of a long sheath.^{11,12} These balloons were expanded to the maximal rated pressure. After initial deployment, the stents were further expanded as necessary with balloons of larger diameter, or capable of withstanding higher-pressures, so as to leave the minimal residual stenosis. Written informed consent for implantation of the stents was obtained from the parents of all the patients.

Analysis of data

We retrospectively measured manually various features on either the frontal projection of the angiograms, the left anterior projection with cranial angulation, or the right anterior projection with cranial angulation as seen during initial expansion of the balloon, and again immediately after the withdrawal of the balloon:

- The diameter of the stenotic vessel.
- The minimal diameter of the lumen before and after the procedure.
- The minimal diameter of the largest fully expanded balloon.

When predilatation was performed, we took the diameters as measured after pre-dilation as the diameter prior to the procedure. Magnification was corrected using an appropriately positioned grid similarly to the angiograms. We measured the mean absolute error between 2 observers (HT and KH) by assessing 90 measurements of the initial 30 lesions. We then analyzed the difference in acute recoil associated with the type of stent, and with the various lesions. Subsequently, we investigated the factors contributing to the degree of acute recoil of large Palmaz stents.

Calculations were made as follows:

- The proportional stenosis prior to the procedure was calculated by multiplying the diameter of the stenotic vessel minus the minimal diameter of the lumen prior to the procedure by 100 and dividing by the diameter of the stenotic vessel.
- The ratio of the size of the balloon to the stenotic vessel was calculated by taking the minimal diameter of the largest fully expanded balloon and dividing by the diameter of the stenotic vessel.
- The ratio of the balloon to the site of stenosis was calculated by taking the minimal diameter of the largest fully expanded balloon and dividing by the minimal diameter of the lumen prior to the procedure.
- The absolute recoil, in millimetres, was considered as the minimal diameter of the largest fully expanded balloon minus the minimal diameter of the lumen subsequent to the procedure.
- The proportional recoil was the absolute recoil multiplied by 100 and divided by the minimal diameter of the largest fully expanded balloon.

We measured in systole the minimal diameter of the lumen, and the diameter of the stenotic vessels. The diameter of the stenotic vessel was considered to be the diameter of the segment proximal or distal to the narrowing, whichever was smaller.

Statistics

Data were expressed as mean plus or minus standard deviation. Statistical comparisons were done using Student's unpaired t-test, one-way analysis of variance, and single linear regression function test using the StatView 5.0 software of the SAS Institute, Cary, North Carolina, USA. A p-value less than 0.05 was considered statistically significant.

Results

Variability of measurements between observers

In 90 measurements of 30 lesions, the absolute difference between the two observers ranged from 0 to 1.5 mm, with a standard deviation of 0.4 ± 0.3 mm, and with good correlation of the measurements (Fig. 1).

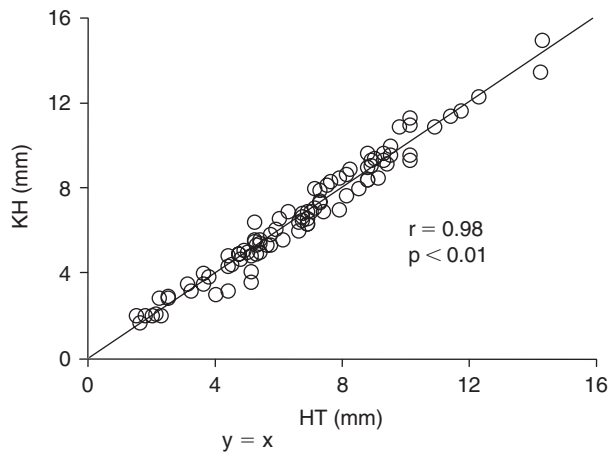


Figure 1. Correlation between the measurements of the two different observers.

Acute recoil according to the types of stent and the variability in lesions

The minimal diameter of the fully expanded balloon, and the minimal diameter of the lumen subsequent to the procedure ranged from 3.9 to 14.3 mm, with mean \pm standard deviation of 8.2 ± 2.4 mm, and from 3.7 to 14.2 mm, with mean \pm standard deviation of 7.7 ± 2.3 mm, respectively, which gave an absolute recoil from between zero and 1.4 mm, with mean \pm standard deviation of 0.5 ± 0.4 mm, and a proportional recoil of between zero and 15%, with mean \pm standard deviation of $7 \pm 0.4\%$ (Table 1). There was, however, considerable overlap between the absolute recoil and the absolute difference between two observers, with the absolute recoil being significantly larger than the difference between observers ($p < 0.05$). Although there was significant difference in diameters of the stenotic vessels, as with the minimal diameters of the lumen before and after the procedure, the minimal diameter of the largest fully expanded balloon, the proportional stenosis prior to the procedure, and the ratio of the size of the balloon to the site of stenosis, there was no significant difference in either the absolute or the proportional recoil for any of the different stents (Table 1). Furthermore, there was no significant difference in either the absolute or the proportional recoil associated with the location of the stenosis in different vessels, despite a significant difference in the measurements taken in the various vessels (Table 2).

Factors contributing to the degree of acute recoil of the large Palmaz stent

After excluding the P 128 stent, which was implanted in only 4 lesions, we found no significant difference in either the absolute or proportional recoil between

Table 1. The acute recoil with the various types of stent (all measurements in mm).

No. of lesions:	Palmaz large (48)	Palmaz medium (12)	Palmaz Corinthian (11)	Total (71)	p
Diameter of vessel	5.0–15.3 (8.9 ± 2.5)	4.6–8.9 (6.4 ± 1.4)	4.0–9.2 (5.1 ± 1.4)	4.0–15.3 (7.9 ± 2.6)	<0.01
Minimal diameter of the lumen before procedure	1.8–10.9 (5.0 ± 2.0)	1.6–4.4 (2.6 ± 0.9)	0.7–4.0 (2.1 ± 1.0)	0.7–10.9 (4.1 ± 2.1)	<0.01
Minimal diameter of the lumen after procedure	5.2–14.2 (8.7 ± 2.0)	3.7–7.4 (5.8 ± 1.2)	4.2–7.9 (5.3 ± 1.2)	3.7–14.2 (7.7 ± 2.3)	<0.01
Diameter of balloon	3.9–14.3 (8.2 ± 2.4)	3.9–8.4 (6.3 ± 1.4)	4.5–7.9 (5.7 ± 1.1)	3.9–14.3 (8.2 ± 2.4)	<0.01
Proportional stenosis (%)	0–76 (43 \pm 19)	34–74 (59 \pm 11)	10–86 (57 \pm 19)	0–86 (48 \pm 19)	<0.01
Ratio of balloon to diameter of vessel	0.78–1.48 (1.07 ± 0.16)	0.74–1.22 (1.01 ± 0.17)	0.86–1.38 (1.13 ± 0.14)	0.74–1.48 (1.07 ± 0.16)	ns
Ratio of balloon to stenosis	1.01–5.00 (2.09 ± 0.76)	1.50–3.62 (2.60 ± 0.70)	1.25–8.29 (3.18 ± 1.84)	1.01–8.29 (2.34 ± 1.05)	<0.01
Absolute recoil	0–1.4 (0.6 ± 0.4)	1.0–1.2 (0.5 ± 0.3)	0–0.7 (0.4 ± 0.2)	0–1.4 (0.5 ± 0.4)	ns
Proportional recoil (%)	0–15 (6 ± 4)	2–14 (8 ± 4)	0–14 (7 ± 5)	0–15 (7 ± 4)	ns

Table 2. Acute recoil in various lesions.

No. of lesions:	Pulmonary artery (37)	Aorta (13)	Pulmonary vein (10)	Superior vena cava (7)	Others (4)	P
Diameter of vessel	4.4–13.0 (7.8 ± 2.0)	4.7–15.3 (6.7 ± 4.3)	4.0–8.4 (5.2 ± 1.3)	10.6–12.4 (11.6 ± 0.7)	5.0–5.4 (5.1 ± 0.2)	<0.01
Minimal diameter of the lumen before procedure	1.8–10.9 (4.4 ± 2.1)	1.5–8.5 (4.5 ± 2.1)	1.5–3.6 (2.4 ± 0.7)	3.8–7.8 (5.7 ± 1.2)	0.7–1.6 (1.4 ± 0.5)	<0.01
Minimal diameter of the lumen after procedure	5.2–12.0 (7.8 ± 1.7)	4.4–14.2 (8.2 ± 2.5)	3.7–8.5 (5.1 ± 1.4)	9.5–11.9 (10.9 ± 0.9)	4.4–5.2 (4.7 ± 0.4)	<0.01
Diameter of balloon	5.2–12.0 (8.4 ± 1.7)	5.0–14.3 (8.8 ± 2.5)	3.9–9.1 (5.5 ± 1.4)	10.1–12.8 (11.7 ± 0.9)	4.8–5.8 (5.2 ± 0.5)	<0.01
Proportional stenosis (%)	0–76 (43 ± 21)	33–74 (50 ± 14)	10–68 (53 ± 17)	33–65 (51 ± 11)	68–86 (73 ± 9)	ns
Ratio of balloon to vessel	0.74–1.48 (1.10 ± 0.18)	0.87–1.40 (1.01 ± 0.14)	0.81–1.24 (1.08 ± 0.15)	0.90–1.21 (1.01 ± 0.10)	0.89–1.16 (1.01 ± 0.11)	ns
Ratio of balloon to stenosis	1.01–5.00 (6.59 ± 4.89)	1.35–3.62 (2.22 ± 0.78)	1.25–3.33 (2.44 ± 0.61)	1.54–2.66 (2.11 ± 0.35)	3.00–8.29 (4.38 ± 2.60)	ns
Absolute recoil	0–1.4 (0.5 ± 0.4)	0–1.3 (0.5 ± 0.4)	0.1–0.7 (0.4 ± 0.2)	0.4–1.1 (0.8 ± 0.2)	0.3–0.6 (0.5 ± 0.1)	ns
Proportional recoil (%)	0–15 (7 ± 5)	0–15 (6 ± 4)	2–14 (8 ± 4)	3–10 (7 ± 2)	6–10 (9 ± 2)	ns

the P308 and a P188 stents, even though there were significant differences in the measurements of the various vessels undergoing dilation (Table 3). We implanted a large stent in only one pulmonary vein. There was no significant difference, however, in either the absolute or proportional recoil between the lesions dilated in the pulmonary arteries, the aorta, and the superior caval vein, again despite significant differences in the measurements of the various vessels (Table 4).

The proportional recoil correlated linearly with the ratio of the size of the balloon to the diameter of the site of stenosis, and with the minimal diameter of the lumen prior to the procedure. In contrast, there was no significant correlation between the proportional recoil and the other measurements made (Table 5). The proportional recoil exceeded one-tenth when the ratio of the size of the balloon to the diameter at the site of stenosis was greater than 3.0, or the minimal diameter of the lumen prior to the procedure was less than 3 mm (Fig. 2).

Discussion

Early vascular recoil is an important contribution to early restenosis following conventional balloon angioplasty. Although a stent is much more effective in diminishing recoil, immediate recoil of the stent itself may be one of the major determinants of suboptimal expansion, and subsequent late restenosis.^{7–10} Late restenosis complicated by neointimal proliferation is usually a less important issue in great vessels, such one of the branches of the pulmonary trunk, the aorta, or the superior caval vein, than it is in coronary arteries.^{4,6} Occasionally, nonetheless, excessive intimal proliferation occurs immediately proximal or distal to any residual waist within the stent, even in great vessels.⁶ Currently, stents have been used extensively to dilate stenotic congenital cardiac malformation in younger children.^{11–14} We recently reported the association of a late luminal decrease after stenting and the final achieved diameter in the pulmonary arteries,¹⁵ which suggests that issues of late restenosis should not be disregarded even in great vessels, particularly in young patients.^{13,15} Previous experimental and clinical studies of intervention in the coronary arteries have shown that increased injury to the wall of the vessel by over-dilation can promote intimal hyperplasia.^{16–18} To determine the optimal diameter of the balloon used to expand a stent, therefore, demands knowledge of the appropriate balance between acute recoil and over-dilation.

Reports of the magnitude of immediate recoil of coronary arterial stents vary from 3.5 to 17%,^{19–22} albeit that, to our knowledge there are no reports regarding the acute recoil of large or medium stents.

Table 3. Acute recoil and length of the large Palmaz stent.

No. of lesions:	P308 (26)	P188 (18)	P128 (4)	p
Diameter of vessel	5.7–15.3 (10.2 ± 2.4)	6.0–11.0 (7.6 ± 1.5)	5.0–7.9 (6.6 ± 1.3)	<0.01
Minimal diameter of the lumen before procedure	2.8–10.9 (5.5 ± 1.9)	1.9–9.7 (4.6 ± 2.0)	1.8–5.1 (3.5 ± 1.4)	ns
Minimal diameter of the lumen after procedure	5.6–14.2 (9.6 ± 1.9)	5.2–12.0 (8.0 ± 1.7)	5.3–7.4 (6.7 ± 0.9)	<0.01
Diameter of balloon	6.0–14.3 (10.1 ± 1.9)	5.2–12.0 (8.6 ± 1.7)	5.9–7.5 (6.9 ± 0.7)	<0.01
Proportional stenosis (%)	0–70 (45 ± 18)	0–76 (40 ± 21)	35–64 (48 ± 12)	ns
Ratio of balloon to vessel	0.78–1.40 (1.01 ± 0.13)	0.85–1.48 (1.15 ± 0.17)	0.87–1.23 (1.07 ± 0.16)	<0.05
Ratio of balloon to stenosis	1.01–3.36 (1.99 ± 0.57)	1.04–5.00 (2.21 ± 0.98)	1.35–3.28 (2.21 ± 0.82)	<0.01
Absolute recoil	0–1.3 (0.6 ± 0.4)	0–1.4 (0.6 ± 0.4)	0–0.6 (0.3 ± 0.3)	ns
Proportional recoil (%)	0–15 (6 ± 4)	0–15 (7 ± 5)	0–10 (4 ± 5)	ns

Table 4. Acute recoil of the large Palmaz stent in various lesions.

No. of lesions:	Pulmonary artery (30)	Aorta (10)	Superior vena cava (7)	Pulmonary vein (1)	p
Diameter of vessel	5.0–13.0 (8.0 ± 1.9)	5.7–15.3 (9.7 ± 3.2)	10.6–12.4 (11.6 ± 0.7)	8.4	<0.01
Minimal diameter of the lumen before procedure	1.8–10.9 (4.8 ± 2.2)	3.5–8.5 (5.3 ± 1.7)	3.8–7.8 (5.7 ± 1.2)	3.6	ns
Minimal diameter of the lumen after procedure	5.2–12.0 (8.1 ± 1.7)	6.9–14.2 (9.0 ± 2.5)	9.5–11.9 (10.9 ± 0.9)	8.5	<0.01
Diameter of balloon	5.2–12.0 (8.7 ± 1.7)	6.9–14.2 (9.5 ± 2.4)	10.1–12.8 (11.7 ± 0.9)	9.1	<0.01
Proportional stenosis (%)	0–76 (41 ± 22)	33–69 (44 ± 11)	33–65 (51 ± 11)	57	ns
Ratio of balloon to vessel	0.78–1.48 (1.10 ± 0.17)	0.87–1.40 (1.01 ± 0.15)	0.90–1.21 (1.01 ± 0.10)	1.10	ns
Ratio of balloon to stenosis	1.01–5.00 (6.37 ± 4.65)	1.35–3.04 (1.89 ± 0.52)	1.54–2.66 (2.11 ± 0.35)	2.50	ns
Absolute recoil	0–1.4 (0.5 ± 0.4)	0–1.3 (0.6 ± 0.4)	0.4–1.1 (0.8 ± 0.2)	0.6	ns
Proportional recoil (%)	0–15 (6 ± 5)	0–15 (6 ± 5)	3–10 (7 ± 2)	7	ns

Table 5. Factors that contribute to the degree of acute recoil.

	r	p
Diameter of vessel	0.21	ns
Minimal diameter of the lumen before procedure	0.34	<0.05
Diameter of balloon	0.15	ns
Proportional stenosis	0.24	ns
Ratio of balloon to vessel	0.23	ns
Ratio of balloon to stenosis	0.37	<0.05

Of the stents we studied, the Palmaz Corinthian IQ transhepatic stent is a novel biliary stent that has improved deployment flexibility compared to the original rigid Palmaz stent.^{11,12} It can be deployed thorough a sheath, of 6 French size, whilst its radial strength is reported to equal that of the original medium Palmaz stent. In our study, both the absolute and proportional recoils were comparable for the 3 types of stent. Although the average absolute recoil was slightly greater than reported for the coronary arterial Palmaz-Schatz stent, the average proportional recoil was similar. Location of the stenosis had no impact on the degree of acute recoil. As radial strength is a major determinant of immediate recoil, there should be no significant difference in radial strength of these types of stent, at least in the clinical settings we studied.

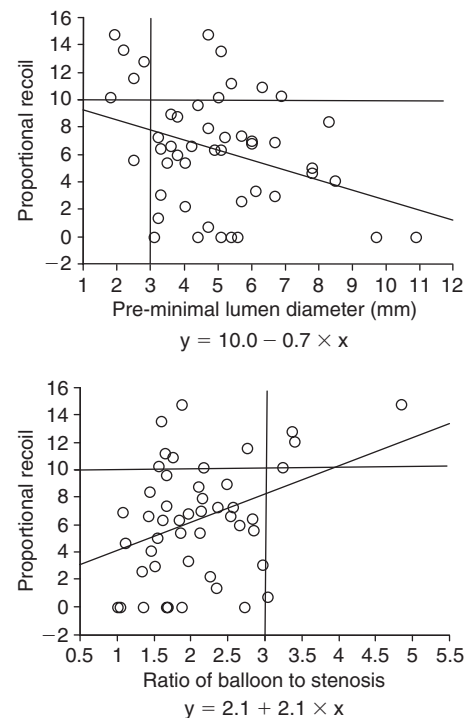


Figure 2. At the top is shown the relationship between the proportional recoil and the minimal diameter of the lumen prior to the procedure, while at the bottom is seen the relationship between the proportional recoil and the ratio of the diameter of the balloon to the site of stenosis.

The length of large Palmaz stent, and the type of lesion dilated, also had no significant impact on proportional recoil. Among the features measured, the diameter of the balloon, the minimal diameter of the lumen prior to the procedure, and the ratio of the size of the balloon to the diameter of the site of stenosis all correlated roughly with the proportional recoil. The lesions dilated in our study, however, were mostly postoperative, and we were unable to determine any relationship between previous surgical methods and immediate recoil because of the many methods and materials used in a relatively small number of lesions. The large Palmaz stents are usually delivered mounted on low profile balloons of 8, 10, or 12-mm diameter, thus providing a uniform caliber to the vessel without overdilating its wall.^{1,2,4-6} Following such deployment, a second balloon with a larger diameter is occasionally required to optimize dilation. For this purpose, some have used a balloon 10% larger to implant a stent in conduit from the right ventricle to the pulmonary arteries,²³ while others selected a balloon having a diameter 1 mm greater than the diameter of the proximal aortic isthmus in patients with coarctation of the aorta.²⁴ To minimize the medical resources required, we recommend a balloon having a diameter approximately 10% greater to implant large Palmaz stents when the minimal diameter of the lumen prior to the procedure is less than 3 mm, and the ratio of the balloon to the stenosis is greater than 3.0. In such a situation, predilation may reduce the amount of recoil of the stent. We could not confirm this opinion, however, since prior dilation was performed in only a few patients, and we took the diameters prior to the predilation as the diameters prior to the procedure.

There are some limitations to our study. The relatively large variability of the measurements between the observers, compared to the small absolute and proportional recoils, may limit the significance of our findings. The absolute recoil, nonetheless, was still significantly larger than the variability between the observers, and the correlation between the two observers was good. Consequently, we believe our measurements are reliable. Although the absolute and proportional recoils were not different for any of the stents used, nor for different types of stenosis, there was a wide variation in the length of stents and the characteristics of the lesions, as well as the surgical procedures and the materials used for surgery. The stiffness of the lesion and the radial strength of the stents is probably a major determinant of immediate recoil, although we did not measure stiffness itself. Further studies are necessary, therefore, to investigate the properties of the stenotic lesions, and the differences in acute recoil that may depend on the different diameters of the various vessels, particularly in young children.

In conclusion, we have shown that absolute recoil of around 1 mm is not uncommon when medium or large Palmaz stents, or the Palmaz Corinthian stent, are expanded in the great vessels. Balloons with a diameter approximately one-tenth greater than that of the adjacent vessel may be needed in the measured minimal diameter of the lumen prior to dilation is small.

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