Immediate stent recoil: a forgotten phenomenon

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Abstract

We sought to measure *immediate* stent recoil (before *vs.* after deflation of the deployment balloon) in diseased coronary artery segments. *Immediate* recoil has not been assessed since the early days of stenting.

We performed a prospective study in 120 consecutive, high pressure-stented coronary artery lesions. Angiographic images of the stent on the balloon during final balloon inflation, and of the treated segment of artery immediately afterwards, were recorded in two projections. The unconstrained balloon was measured at nominal pressure in the aorta for validation. Measurements were made blind, off-line. Comparison was made with the diameters quoted by the manufacturer for the balloon pressures used.

The stent deployment pressure was 12.82(SEM 0.30) atm. Measurement of the balloon at nominal pressure in the aorta disclosed an accuracy of 99% (the manufacturer's stated balloon/stent diameter at nominal pressure was 3.16[0.07] mm and the measured value was 3.20[0.07] mm). The manufacturer's stated balloon/stent diameter at deployment pressure was 3.37(0.05) mm ('100%'), whereas the balloon/stent in the diseased segment measured 3.23(0.05) mm (96[1.5]%) and the final stented segment measured 3.02(0.05) mm (90[1.5]%) ($p<0.0001$ for all).

Even using contemporary stents at high pressure, undersizing of the stent occurs by 4% compared to the manufacturer's stated size at deployment pressure. There is immediate recoil of a further 6% when the balloon is deflated, presumably due to constraint by the surrounding atherosclerotic vessel. Stents may prevent late, but not immediate, recoil. The stented segment diameter is 10% smaller than intended.

Key words: coronary angioplasty, stents, recoil.

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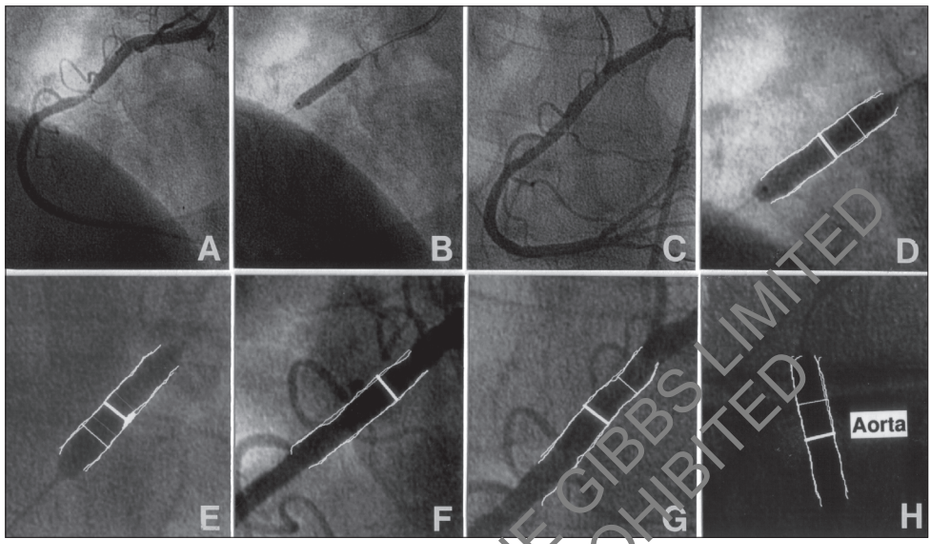
Introduction

After balloon dilatation of a stenosed coronary artery segment, as much as 23% (0.42 mm) of the acute gain can be lost as soon as the deploying balloon is deflated.[1] This loss of luminal diameter may be termed *immediate recoil*. It is widely known that stents achieve better acute (and, to some extent, long-term) results than balloon angioplasty in achieving (and maintaining) a smaller post-procedural residual stenosis by preventing *acute* (and *chronic*) recoil.[2,3] The latter two are measured from the time after the deployment balloon is deflated until the end of the procedure or at a later time-point, respectively. Acute and chronic recoil may be measured readily using intravascular ultrasound imaging (IVUS).[4] *Immediate* recoil is not amenable to IVUS assessment, because however rapidly the deploying balloon and the IVUS catheter are inserted, immediate recoil has already occurred.

Haude *et al.* studied immediate recoil in 1993 in the 'slotted tube' Palmaz-Schatz stent.[5] The immediate recoil in the stent group was 0.10±0.07 mm in a vessel of reference diameter 3.30±0.43 mm (about 3%), comparing favourably with a figure after balloon angioplasty of 0.98±0.50 mm in a vessel of 3.22±0.47 mm (about 30%).[5] In the Stent REStenosis Study Investigators (STRESS) study (in which the Palmaz-Schatz stent was also used), immediate recoil in the stent group was 15±11%, but this was taken to be a favourable result, because the corresponding figure for the balloon angioplasty group was 24±15%.[6] The reduction in acute recoil achieved with stenting (compared with balloon angioplasty) contributed to the establishment of stenting as routine in the percutaneous treatment of coronary artery disease.

Also of relevance to the question of immediate recoil is the information provided by the stent manufacturer. This is usually supplied, in the packaging of each balloon/stent, as a table of diameters achieved by the stent over a range of balloon pressures. These measurements are obtained at bench-top testing, and reflect the balance between the expansile effect of the fluid in the balloon against the constraining effect (compliance) of the balloon material and the stent. These figures are often referred to during percutaneous coronary intervention (PCI), and are widely believed to be accurate. These measurements make no

Figure 1. A 62-year-old man presented with chronic stable angina and a high-grade stenosis in the proximal right coronary artery **(A)**. This underwent stent implantation **(B)** with a 3.5x15 mm Lekton stent (Biotronik), with full stent expansion at 14 atm (manufacturer's stated diameter at this pressure=3.65 mm). There was an excellent angiographic result **(C)**. The difference in diameter between **(B)** and **(C)** is termed *immediate recoil*. Automated quantitative analysis was made, in two orthogonal views, of the inflated balloon/stent in the lesion **(D,E)** and of the stented segment afterwards **(F,G)**. The balloon was then inflated at nominal pressure (10 atm) in the aorta, and the measurements repeated **(H)**. Measurements were made at one half and one quarter of the distance along the stent/segment



allowance, however, for the potentially constraining effects of a surrounding atherosclerotic lesion.

We hypothesised therefore that, even with modern stents and deployment methods: there is significant immediate recoil of the stent in the lesion; and the manufacturer's stated balloon/stent size for a given deployment pressure is an underestimate in a diseased artery.

Methods

Study design

We performed a prospective study of consecutive, successfully-stented coronary artery lesions in patients undergoing either routine elective or emergency PCI, performed by a single operator (JG) in a teaching hospital. There were no patient-related inclusion or exclusion criteria. The only criteria related to the procedure, the artery and the stent. The angioplasty was performed according to standard modern practice. The stent must have been successfully deployed, as assessed by the presence of TIMI grade III flow and by the lack of any significant residual stenosis on 'eyeball' assessment of the final angiograms by the operator. The arterial lesion morphology or degree of calcification were not investigated, simply the quality of stent deployment by visual assessment. Care was taken to ensure that the stents were deployed at a pressure greater than that quoted by the manufacturer as 'nominal'.

Angiographic protocol

Two clear views of the stent were required, in orthogonal projections wherever possible, free of visual overlap from other vessels, near the centre of the frame (to avoid 'pin-cushion' distortion), and with good quality images of the guide catheter, which was used for calibration. Any number of stents could be studied in any one patient, provided the lesion-based criteria described above were met for each stent. The contrast:saline ratio for balloon inflation was 3:1 to provide maximum clarity for quantitative coronary angiographic (QCA) measurements of the balloon, which were performed 'off-line' at the end of the procedure.

Digital images of the stent on the balloon were obtained during final balloon inflation (to assess the actual stent size achieved), and of the treated segment of artery during the final angiogram (to assess immediate recoil). Where the dilatation was judged inadequate by the operator and further dilatation was undertaken, the diameters of the final balloon were used and the QCA angiograms were repeated in both projections. The accuracy of the QCA was validated by measurement of the unconstrained balloon, inflated to nominal pressure, in the aorta at the end of the procedure.

Images were recorded using an Integris HM3000 system and transferred, by LAN ethernet, to an Easivision RF/R2 workstation for off-line measurement (all supplied by Philips Medical Systems, Best, The Netherlands).

Stent and artery measurements

The angioplasty operator (JG) was blinded to the QCA, and the radiographer performing the QCA (JB) was blinded to the sizes

of the balloon and stent. The measurements of the balloon/stent and the corresponding stented segment were made at points approximately one quarter and one half of the distance along the stent in each projection to avoid the confounding effect of tapering at the ends of the balloon. The stent and artery diameters were compared with the diameter of the balloon/stent quoted by the manufacturer for the final dilatation pressure used. The end point was the collection of a full set of QCA and manufacturer's data for each patient.

Statistics

The four measured diameters of the balloon/stent and stented arterial segments (two for each of two projections) were averaged and expressed, for the whole population, as mean (SEM). These measurements were also expressed as percentages of the manufacturer's ideal at the pressure used for deployment. The actual balloon/stent diameters achieved were compared with the ideal, and with the final arterial diameters, with paired Student's t-tests. Significance was sought at the 95% level.

Results

Patients, stents and lesions

A total of 120 consecutive stented lesions which fitted the criteria laid out above were studied in 82 patients. Sixteen lesions were excluded due to inadequate imaging or recording of images. The 104 remaining lesions were derived from 74 patients, of whom 53 (72%) were male, and their age was 63(1.0) years. In all, 45% of the stents were placed in the left anterior descending, 22% in the circumflex, 27% in the right coronary artery and 6% in other vessels. The stents used were: Bio*divYsio* (Biocompatibles, Farnham, UK) in 64%; Coroflex (B-Braun, Sheffield, UK) in 17%; S7 (Medtronic, Minneapolis, MN) in 12%; and others in 11%. The nominal stent diameter was 3.16(0.04) mm, the final deployment pressure was 12.9(0.31) atm and the stent length was 14.3(0.60) mm. There were no major procedural complications (a prerequisite of inclusion), no cases of in-hospital coronary artery bypass graft (CABG) or death, and all patients were well when they left hospital.

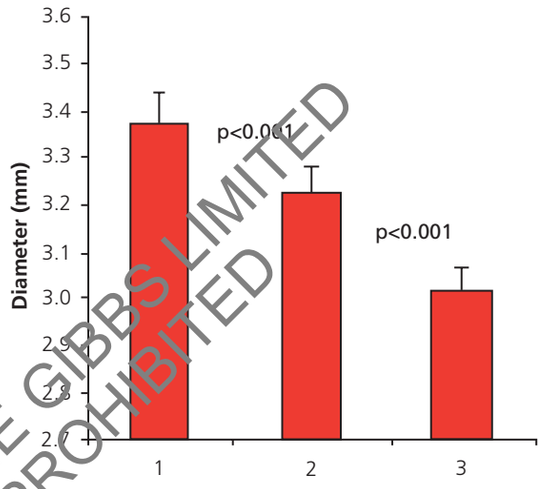
Measurements of stented arteries and recoil

The diameter of the fully expanded balloon/stent, according to the manufacturers' tables, should have been 3.37(0.05) mm. Our measurement of this parameter in the diseased segment of artery was 3.23(0.05) mm, 96% of the manufacturers' stated diameter ($p<0.00001$). Our measurement of the final luminal diameter of the stented segment of artery was 3.02(0.05) mm, 90% of the manufacturers' stated diameter ($p<0.00001$). Figure 1 shows examples and figure 2 shows aggregated data for balloon stent diameter.

Influence of stent calibre

The data were subdivided into three groups according to stent diameter: 2.5 and 2.75 mm (24% of stents); 3.0 mm (36% of stents); and 3.5 and 4.0 mm (40% of stents). The immediate recoil was almost identical in all three groups (table 1).

Figure 2. Comparison of diameters: 1) manufacturer's quoted balloon/stent diameter at deployment pressure; 2) the measured balloon/stent diameter in the lesion at deployment pressure; 3) the final diameter of the stented segment. The difference between columns 1 and 2 represents under-achievement of the intended stent size. The difference between columns 2 and 3 represents *immediate stent recoil*. The final result (column 3) is 10% smaller than the intended diameter (column 1)



Influence of stent type

The data were subdivided according to the three commonest stent types used in this study (Bio*divYsio* [64%], Coroflex [17%] and S7 [12%]). Whilst the Coroflex and Bio*divYsio* stents are manufactured from a steel tube, the former have fewer longitudinal connecting struts and more open cells. The S7 stent is a 'coiled wire' with a greater flexibility but less radial strength than the 'slotted tube' designs. There were no differences in deployment pressures between individual stent manufacturers. The degree of recoil was very similar for the first two types (figure 3), but the small number in the S7 group precluded any definite conclusion.

Validation of the QCA

The accuracy of the angiographic measurements, as assessed by measurements of the deployment balloon (unconstrained and inflated at nominal pressure in the aorta) was to within 99% (the measured balloon diameter was 3.20[0.07] mm and the manufacturer's stated size at nominal pressure was 3.16[0.05] mm).

Discussion

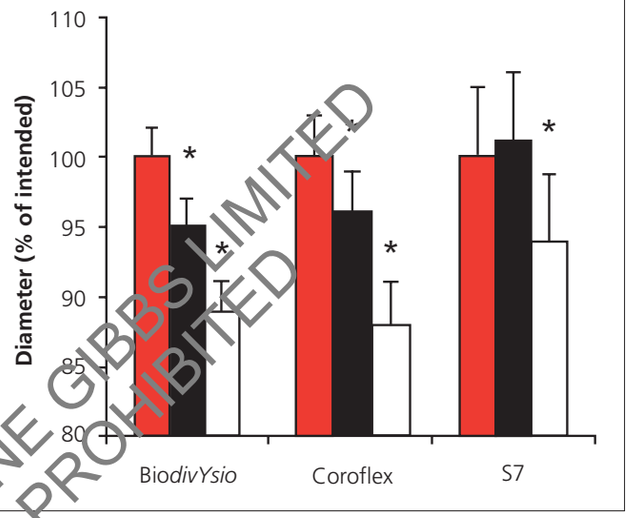
In this simple study we have shown that a coronary artery stent, deployed optimally (according to routine modern clinical criteria), achieves a diameter which is 10% less than that intended. This is because the inflated balloon/stent is 4% smaller than intend-

Table 1. Recoil data divided into small, medium and large stent sizes. The degree of recoil is similar for the whole range of stent sizes

Stent diameter (mm) **% of all stents**	**2.5–2.75** **24**	**3.00** **36**	**3.5–4.0** **40**
Inflation pressure (atm)	12.10	12.80	13.30
SEM	3.00	3.10	3.40
Nominal diameter (mm)	2.81	3.20	3.85
SEM	0.16	0.11	0.31
Balloon/stent diameter (mm)	2.67	3.10	3.63
SEM	0.07	0.04	0.04
% of nominal	95	97	94
Stented segment diameter (mm)	2.54	2.86	3.39
SEM	0.07	0.05	0.05
% of nominal	90	89	88

Key: SEM = standard error of the mean

Figure 3. Comparison of recoil measurements for the three most frequently used stents in this study: Bio*divYsio* (Biocompatibles), Coroflex (B-Braun), and S7 (Medtronic). Red columns=manufacturer's stated balloon/stent diameter at deployment pressure; black=measured balloon/stent diameter at deployment pressure; white=measured diameter of stented segment of artery. *=p<0.05. *Immediate recoil* is represented by the difference between the black and the white columns. There is an almost identical degree of acute recoil for the first two designs



ed, and the stented segment recoils immediately by a further 6% after deflation of the balloon. This result is valid for all stent sizes and is similar for three currently used stent designs. These data are similar to those obtained with early stent designs a decade ago.

The most obvious explanation for these findings is that stent expansion is constrained by the surrounding diseased segment of arterial wall. It has been axiomatic since their inception that 'slotted tube' stents do not allow arterial recoil (unlike coil stents which possess less radial strength).[7] In fact, the way recoil has been measured (with either QCA or IVUS) has generally not allowed assessment of *immediate*, but rather subsequent (*acute*), recoil because the baseline measurement has been taken at the time of either the angiogram after stent deployment or the IVUS run after this. In the early instances where immediate recoil was measured, the magnitude was 3–16%.[5,6] Our figure of 10% is certainly consistent with these.

More recent studies have compared the degree of immediate recoil using QCA measurement analyses based on measurements of a stent in a single plane.[7,8] Such measurements may be open to greater variation than the use of measurements of a given stent from orthogonal planes. Danzi *et al*. used single plane measurements to measure cross-sectional area at various points within a stent.[7] These measurements were not compared to the manufacturers' sizes for the stents. Hehrlein *et al*. introduced a 'stent delivery balloon expansion ratio' based on the differences in diameter of the inflated balloon at stent delivery deployment pressure.[8] Stent performance based on immediate recoil was also measured.

In both these studies, similar degrees of recoil were obtained at similar inflation pressures to our study but post-dilatation effects were not incorporated into the result. Our study extends this work by demonstrating that recoil still exists when visual assessment suggests optimal stent deployment. By including post-dilatation procedures as the final intervention which was incorporated into our results, we have shown that 'real world' procedures still result in significant immediate loss of stent calibre.

Since the object of this study was to investigate the immediate recoil of an implanted stent, we deliberately did not investigate the morphology of the vessel wall. Further study may determine if our results are due to our study population having a greater prevalence of coronary calcification, which could create a greater degree of recoil than would have occurred with earlier studies. Similarly, the effects of recoil may be influenced by stenting an acute unstable plaque, as in primary PCI in the treatment of acute myocardial infarction. This also requires future study.

Could our finding be explained in any other way? The system of QCA used here could have introduced a systematic under-estimate of the diameter of any object measured. For this to be the case, it would be necessary to postulate that it under-estimated the size of the stented arterial segment (10%) significantly more than the balloon/stent assembly (4%) or the balloon at nominal pressure, unconstrained (1%). This seems unlikely. It would also be necessary to disregard the findings of previous investigators.[5,6]

What are the implications of our findings and what is their practical importance? Stent deployment in the present study conformed to everyday standard clinical practice. With a mean final balloon pressure of > 12 atm, recoil cannot be attributed to using too low a deployment pressure. Hanekamp *et al*. showed that optimum stent deployment, according to QCA, IVUS and myocardial fractional flow reserve criteria, can be

Key messages

- Immediate recoil refers to loss of the acute gain as soon as the deploying balloon in a stenosed coronary artery segment is deflated
- The study showed that a coronary artery stent, when deployed optimally, achieves a diameter which is 10% less than that intended
- Interventionists should be encouraged to examine the final angiographic result rigorously

achieved using a pressure > 12 atm.[4] Haude *et al.*, like us, showed that immediate recoil occurred across the range of stent sizes to a similar degree (in contrast to their balloon-only group, in which larger balloons were associated with greater recoil).[5] The use of deployment pressure beyond 12 atm with a semi-compliant balloon would tend to oversize the stent but would carry the risk of end-dissection. It would be unfortunate to trade a potentially lower restenosis rate for a higher acute complication rate with this approach. A non-compliant balloon taken to high pressure might achieve the desired result in terms of stent diameter. However, there is no guarantee of abolishing the acute recoil which we have documented, because this occurs after balloon deflation and probably depends more on lesion characteristics and stent hoop strength than balloon inflation parameters.

Perhaps there is scope to improve an operator's assessment of what comprises an 'optimal' result. This judgement of 'optimal' stent deployment (implying 0% residual stenosis) may be, in fact, as much as 16% residual stenosis by QCA.[4] Also, in IVUS-controlled studies, a consistent tendency to under-size on the basis of the angiogram has been found; and, when IVUS is used to optimise sizing, as much as a 23% increase in stent mean luminal diameter can safely be achieved, with a concomitant reduction in target vessel revascularisation to single figures at six months.[3,9] Therefore, one possibility for pragmatic clinical improvement, apart from using IVUS, might be to use cautious increments in balloon pressure (perhaps using QCA in two views) to achieve perfectly cylindrical deployment. A separate prospective study would be required to address this question.

Another way of reducing immediate recoil would be to modify stent or strut geometry, although this would have to be done without sacrificing flexibility. This may be readily achievable by design modification. In the present study, for example, rather to our surprise we found almost identical degrees of acute recoil in the Coroflex and the Bio*divYsio* stents, even though the former is more flexible than the latter. It may also be possible to develop alloys with improved characteristics of both radial strength and flexibility. However, the advent of drug-eluting stents may make this sort of refinement irrelevant if the amount of restenotic tissue can be significantly and permanently reduced by pharmacological means.

Conclusions

We have shown that 'real world' stent implantation, using moderately high deployment pressures, does not achieve the expected in-stent calibre even when the result is judged optimal by the operator. Typically, the diameter achieved is 90% of that expected, a figure that has probably not improved much in the last decade. The most likely explanation for 10% immediate recoil is the constraint imposed upon the stent by the diseased artery. Interventionists should be encouraged to rely on rigorous examination of the final angiographic result, perhaps in two views, rather than rely upon the manufacturer's stated balloon/stent dimension at the final stent deployment pressure, because this is a considerable over-estimate of what is actually achieved.

Conflict of interest

None declared.

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