



# Coronary balloon catheter tip damage. A bench study of a clinical problem

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## Abstract

**Objectives:** To confirm clinically that coronary balloon catheter tips may be damaged during bifurcation treatment with side-branch access through the side of a stent. On the bench, we aimed to assess the susceptibility of different balloon designs to damage. We compared catheter tip widths. We tested whether balloon tip flaring can cause stent distortion.

**Background:** We had observed that balloon catheters that failed to cross to a side-branch frequently exhibited tip damage.

**Methods and Results:** We examined microscopically for damage 82 balloon tips after clinical side-branch access. In a bench study, the forces required to compress catheter tips 0.5 mm were compared to assess susceptibility to damage. We compared tip widths of balloons of different nominal inflation diameters. We examined stents after side-branch access for distortion. In 42 of 48 (88%) of balloon tips from patients with resistance to or failure to cross through the side of a stent there was tip damage. Even when the balloon crossed without perceptible resistance, tip damage occurred in over half of balloons 18/34 (53%). Some balloon designs were more resistant to damage than others. Tips from balloons of different nominal diameters from the same manufacturer had the same width. Stent distortion caused by damaged balloon tips is improved by kissing balloon post-dilatation.

**Conclusions:** Balloon tip damage is common with crossing between stent struts. This is one cause of failure of a balloon to access a side-branch and a new balloon should be used. If stent distortion is suspected, it should be corrected with kissing balloon post-dilatation.

## KEYWORDS

balloon tip damage, bench test, bifurcation

## 1 | INTRODUCTION

Treatment of coronary bifurcation lesions is more challenging and is associated with more complications than treatment of simple lesions [1,2]. Side branch access through the side of a stent by a wire and a balloon may be needed for optimal bifurcation treatment [3] but this may be challenging.

We have observed that one cause of obstructed passage of a balloon between stent struts to the side-branch is damage to the balloon catheter tip (Figure 1) [4]. A damaged, flared tip can catch on a stent or scaffold strut preventing passage to the side-branch and in addition may lead to displacement of stent struts and stent distortion [4–6].

In this study, we aimed to confirm that balloon tip damage occurs clinically with successful and unsuccessful side-branch access.

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**FIGURE 1** Balloon catheter tips retrieved from patients. The left most panel shows an undamaged tip. The rightward 3 panels show damaged balloon tips from 3 different manufacturers. While in these examples the flaring is marked, if of lesser degree it may not be detectable with the naked eye

Furthermore, to compare the susceptibility of different balloon designs to tip deformation, we designed a bench test to measure the force required to shorten a balloon by 0.5 mm. We then inspected the balloons microscopically to see whether this caused permanent tip damage. In addition, we compared widths of balloon tips from different nominal balloon diameters from different manufacturers. On the bench, we examined the potential for flared balloon tips to distort stents.

Our observations may help operators choose an optimal balloon for side branch access. We draw attention to balloon tip damage and flaring as one cause of failure to pass a balloon through the side of a stent to the side-branch. Balloon tip damage may not be visible to the naked eye so it is important to be aware of this potential problem. We assessed whether kissing balloon post-dilatation improved stent distortion caused by catheter tip flaring.

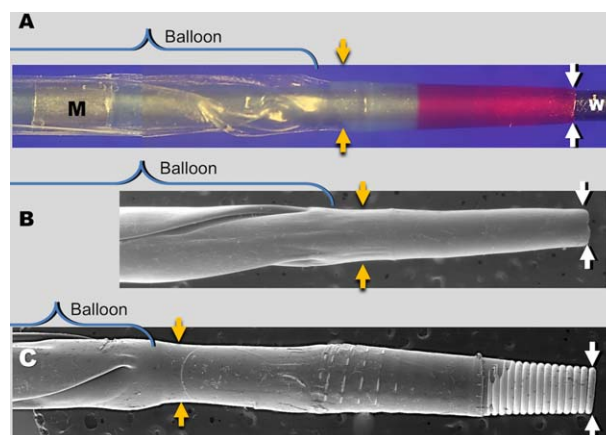
## 2 | METHODS

The structure of the distal end of a percutaneous coronary interventional balloon is shown in Figure 2. The balloon shaft that houses the interventional wire tapers toward the distal tip which is the lesion entry point. The balloon is attached to the shaft at the proximal end of the tapered tip (Figure 2).

### 2.1 | Clinical Study

Balloon catheters used clinically and encountering successful or unsuccessful access to the side-branch through the side of a stent during percutaneous bifurcation intervention were collected for tip evaluation. The operator reported for each balloon the ease of crossing as failed, encountering resistance or no resistance. If more than one advancement of the balloon were required to access the side-branch or if there was a feeling that the balloon briefly caught on a strut, this was called resistance.

The tips of these balloons were evaluated microscopically and photographed with an EOS-1D Canon digital camera (Canon, Inc., Tokyo,

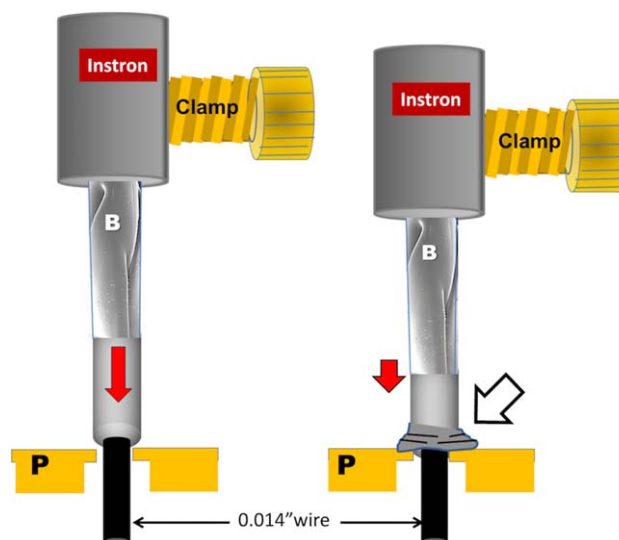


**FIGURE 2** Balloon tip design. The upper panel is a photograph and the lower panels are scanning electron microscopic images of the distal ends of PCI balloons. White arrows indicate the distal tip (entry profile), and the yellow arrows the zone of balloon attachment to the shaft.  $W = 0.014''$  wire,  $M$  = distal balloon radio-opaque marker. The Flexx2 tip design of the Galant balloon (Medinol, Israel) (Panel C) is very different from other designs as it has metal coils reinforcing the tip

Japan) using a Leica Z6 APO microscopic lens (Leica Microsystems, Wetzlar, Germany).

### 2.2 | Compression Study

The apparatus used to measure the force required to shorten balloon tips by 0.5 mm is depicted in Figure 3 and described in the legend. Balloon tips of 3 examples of 2.5 mm nominal diameter balloons from



**FIGURE 3** Apparatus for measuring the force required to shorten a balloon tip by 0.5 mm. A hole fractionally larger than a standard 0.014'' percutaneous interventional wire ( $w$ ) was drilled in a base plate ( $P$ ). A balloon catheter ( $B$ ), advanced over the wire was fixed using the screw clamp so that there was no movement of balloon relative to the wire. The catheter tip rested on the plate ( $P$ ). The clamp was attached to an instron universal testing machine and the force required to shorten the balloon tip by 0.5 mm measured. Flaring of the balloon tip is indicated by the open arrow

each of 12 balloon designs were photographed before and after compression. In addition, each compression was video recorded.

The 12 balloon designs tested were the Accuforce (Terumo Corp, Japan), Emerge (Boston Scientific Corp, Natick, MA), Euphora NC (Medtronic, Santa Rosa, CA), Gallant with Flexx2 tip of (Medinol, Israel), NC Emerge (Boston Scientific), NC Sprinter (Medtronic), NC Trek (Abbott Vascular, Santa Clara, CA), NC Quantum Apex (Boston), Ruygin Plus (Terumo), Sprinter Legend (Medtronic), Tazuma (Terumo), and Trek (Abbott).

### 2.3 | Bench Side-Branch Access Study to Assess Tip Damage and Stent Distortion

Stents were deployed on the bench in a silicone bifurcation model with an angle B[7] of 30° in a water bath. An 0.014" percutaneous interventional wire was passed through the side of the stent to the side-branch then there was attempted balloon access to the side-branch between struts. The balloon passage was recorded cine angiographically. The balloon tips were photographed microscopically before and after side-branch access.

Side-branch access was attempted with a total of 125 SC Trek balloons of 2.5 mm nominal diameter. For each stent design, we tested the passage of 5 balloons through the sides of 5 examples of 5 different stent designs which were Integrity (Medtronic), MultiLink 8 (Abbott Vascular), Onyx (Medtronic), Rebel (Boston), and Synergy (Boston). In addition, the stents were photographed to assess distortion after access by a balloon and the most damaged stents were imaged by microcomputed tomography (microCT). Ease of crossing was recorded as failed, encountering resistance or no resistance. Stent distortion was graded with moderate or severe distortion defined as  $\geq 0.4$  mm malapposition and/or  $\geq 0.4$  mm protrusion into the side branch after 2.5 mm Trek balloon side-branch access.

## 3 | MEASUREMENTS OF DISTAL TIP WIDTHS

The lesion entry profile of 3 balloon catheters for each of 3 nominal balloon diameters (1.25/1.5, 2.5 mm and 3.5 mm) if available from different manufacturers were made from photographs acquired using a microscope. In addition, the widths of balloons at the site of balloon attachment to the shaft were measured before inflation (Figure 2). In general, manufacturers do not make non-compliant 1.5 mm balloons.

### 3.1 | Statistics

Descriptive statistics are presented as mean  $\pm$  SD or counts (%). Differences in categorical values between groups were analyzed using the chi-squared test. Differences in continuous values were analyzed with the Wilcoxon rank-sum test or the Kruskal-Wallis test. The relationship between force applied and compression distance was plotted. Statistical analyses were performed with Microsoft Excel or SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). A p-value  $< 0.05$  was considered statistically significant and all p-values resulted from two-sided tests.

**TABLE 1** Clinical side-branch access success, failure, and tip damage.

Ease of crossing	N	Balloon tip damage	No tip damage
Failed	35	31 (89%)	4 (11%)
Resistance	13	11 (85%)	2 (15%)
No resistance	34	18 (53%)	16 (47%)
Total	82	60 (73%)	22 (27%)

If a balloon failed to cross to the side-branch, there was an almost 90% chance that the balloon tip was damaged. Of balloons that successfully accessed the side-branch, approximately half were damaged.

## 4 | RESULTS

### 4.1 | Clinical Study

Examination of 82 balloon tips from patients after successful or unsuccessful side-branch access through the side of a stent revealed tip damage in 60 (73%) (Table 1). If the balloon failed to cross or if resistance was encountered, there was a high chance of tip damage (89%). (Chi-squared P-value = 0.0023). If crossing was successful without resistance, damage was much less likely (47%) although still occurred.

### 4.2 | Bench Comparison of the Force Required to Compress Balloons of Different Designs by 0.5 mm

The force needed to compress a balloon tip 0.5 mm varies greatly between designs (Figure 4). The Flexx2 and the Trek designs were the most resistant to shortening. The Tazuma (Terumo) was the most easily compressed.

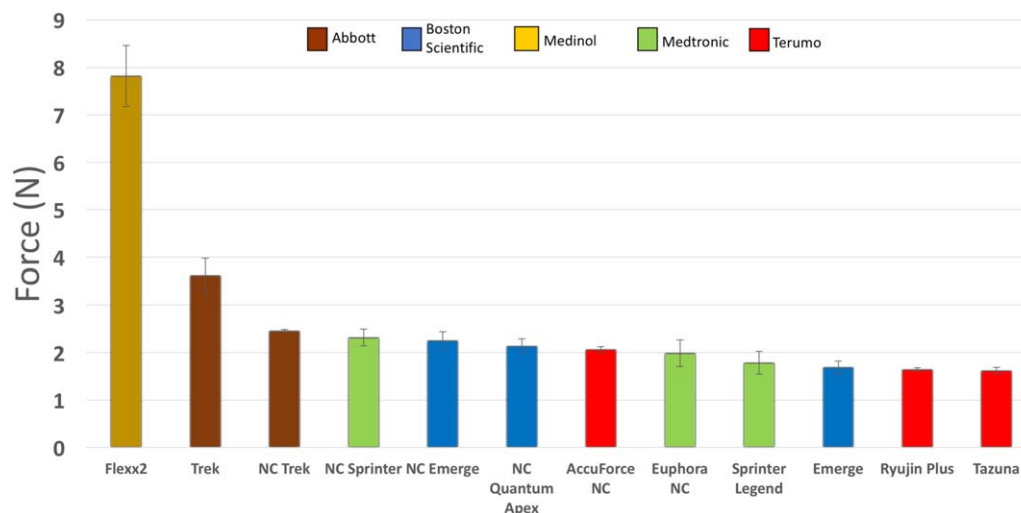
When compressed by 0.5 mm, some balloon tips are damaged whereas others recoiled returning to their original shape (Figure 5 and videos 1–3). The Flexx2 and Trek designs recoiled after compression and had minimal or no damage and all other tips were damaged.

### 4.3 | Measurement of Widths of Distal Balloon Tips (Entry Profile)

No difference in distal balloon catheter tip width (entry profile) was found between the 1.2, 1.5, 2.5 and 3.5 mm nominal diameter balloons of the same design (Figure 6). A balloon with a nominal diameter of 3.5 mm has the same tip width (entry profile) as that of a 1.2/1.5 or 2.5 mm nominal balloon diameter of the same design. The balloon tips of different designs had different diameters.

### 4.4 | Balloon Tip Width at the Level of Attachment of Balloon Material

For each balloon design, the width at the level of balloon material attachment (Figure 2) is greater for non-compliant balloons than semi-compliant balloons and increases with increasing nominal balloon diameter (Figure 7).



**FIGURE 4** The force required to shorten a balloon tip by 0.5 mm is shown on the vertical axis for the 12 balloon designs shown on the horizontal axis. The different colors identify the manufacturer

#### 4.5 | Balloon Tip Damage with Crossing through the Side of a Stent on the Bench

As there were 5 balloon passages across the sides of 5 stents of 5 different designs, there was a total of 125 attempted crossings. Balloon tip damage was present in 35 of 125 passages or attempted passages through the side of a stent. If the balloon did not cross or had impeded crossing then tip damage was present in 22/26 (85%) of instances. This is similar to results from the clinical study. Alternatively, if the balloon passed smoothly without catching there was tip damage in 2/62 (3%) which was much less than in the clinical study.

#### 4.6 | Stent Distortion Induced by a Damaged Balloon Catheter Tip

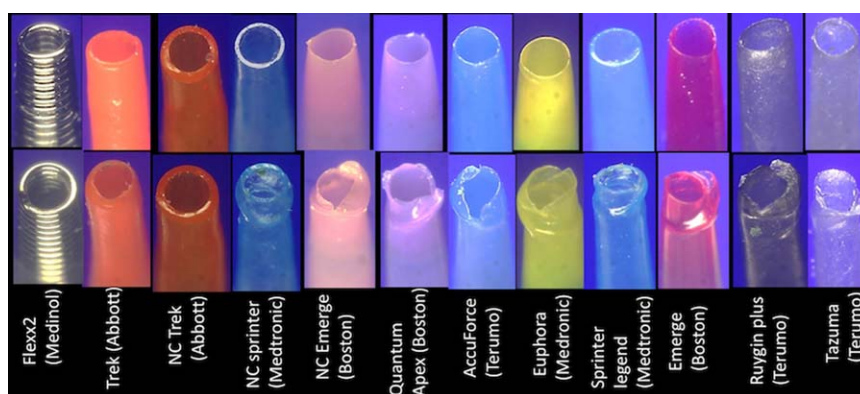
A damaged balloon tip can contact a stent strut pushing it toward the side-branch and distorting the stent. (Figure 8). The distortion can occur with any stent design but appears less common with sinusoidal

wire designs. It can be largely corrected by kissing balloon post-dilatation (Figure 8).

## 5 | DISCUSSION

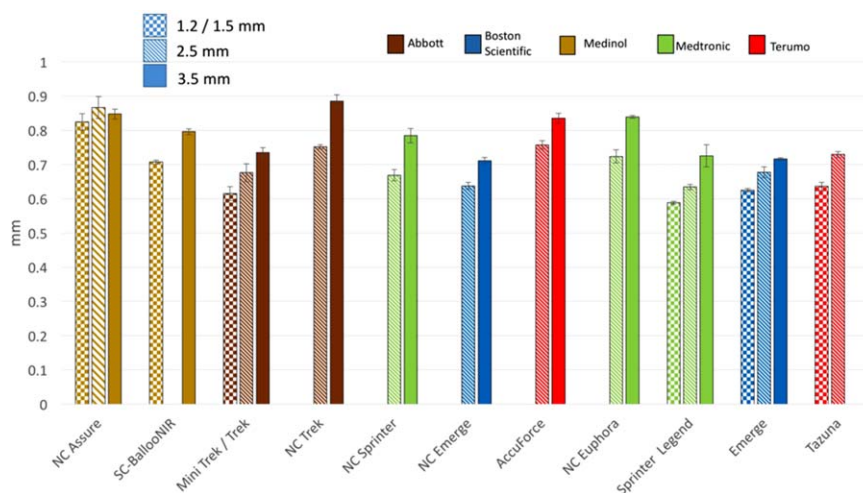
### 5.1 | We Have Shown That

1. Damage and splaying of balloon catheter tips may occur clinically with balloon crossing to a side branch through the side of a stent (Figure 1).
2. Different balloon designs have different susceptibility to tip damage and our bench test showed that the force required to compress balloon tips 0.5 mm differs for different devices with the Flexx2 and Trek balloon designs being most resistant to distortion and the Tazuma design most susceptible (Figures 4 and 5).
3. Balloon tips (entry profiles) of all balloons of the same design but different nominal diameters have the same entry profile width (Figure 6).



**FIGURE 5** Balloon tips and damage with the compression test. In the upper panel are photographs of balloon tips before compression and the lower panel shows the tips after compression. The Flexx2 and Trek designs had no or minimal damage whereas all other designs tested were damaged

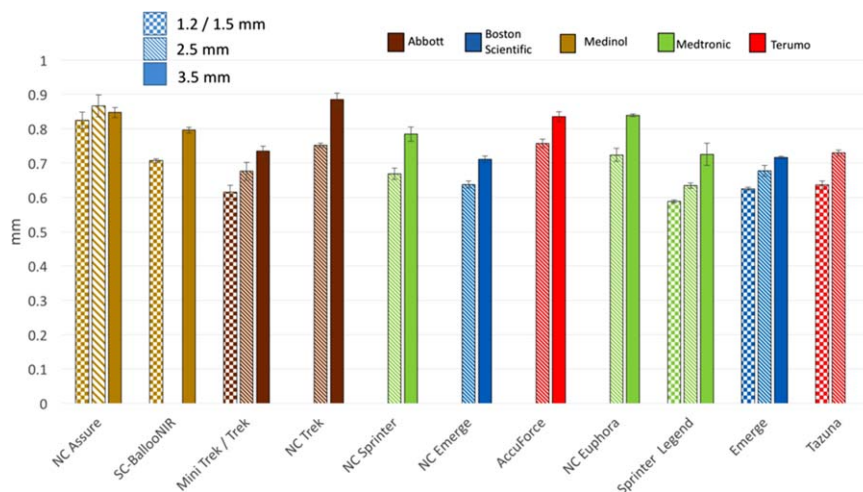




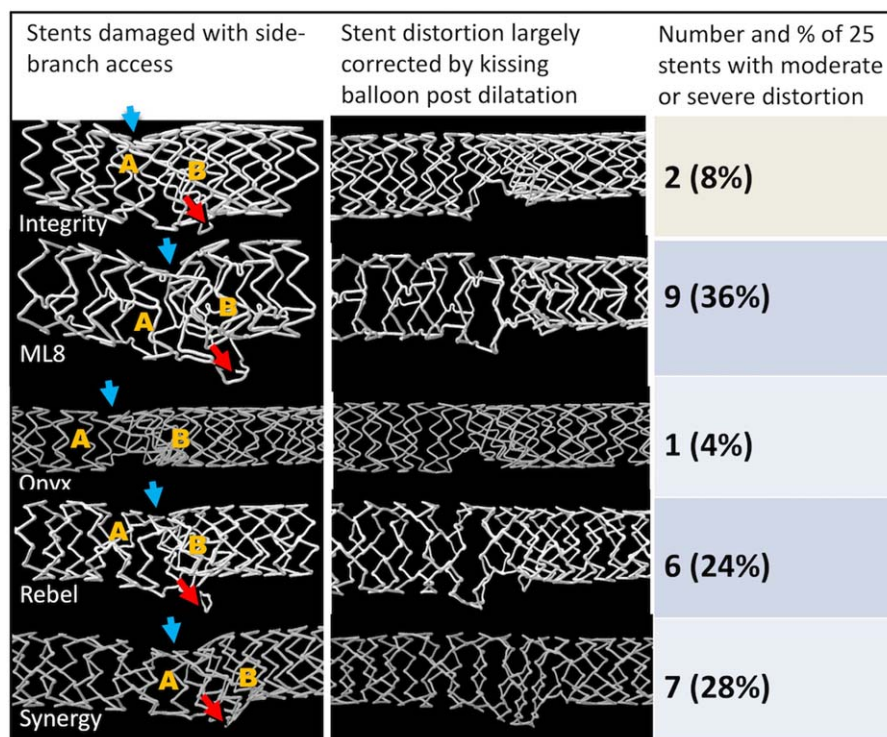
**FIGURE 6** Balloon tip widths (entry profiles) for 1.2/1.5, 2.5, and 3.5 mm balloons. Diameters of balloon tips of different nominal balloon diameters of the same design are the same. For instance, Sprinter Legend of nominal balloon diameters 1.5, 2.5, and 3.5 mm all had the same tip width. Balloons of different designs may have different tip widths. For instance, the Trek and Sprinter balloon tips were wider than the Emerge balloon tips. The Medinol Flexx 2 had the largest catheter tip entry profile

- Balloon tips are tapered. The diameter at the zone of balloon attachment to the shaft is wider than the entry profile (Figure 2). In general, non-compliant balloons are wider at the zone of balloon attachment than semi-compliant balloons of the same nominal balloon size from the same manufacturer presumably because non-compliant balloons have thicker balloon material. In addition, balloons with a larger nominal diameter are wider at the zone of balloon attachment than balloons of lesser nominal diameter of the same design presumably because larger balloons have more balloon material.
- On the bench, balloon tip damage or splaying may prevent access to the side-branch.
- A damaged balloon tip may cause stent distortion when it catches on a strut and pushes it toward the side-branch (Figure 8). This stent distortion can be largely corrected by kissing balloon post-dilatation.

Balloon tip damage can be determined only with difficulty with the naked eye. The damage is one explanation for a balloon failing to cross through the side of a stent into a side-branch. Other explanations include a wire exiting then re-entering the stent lumen outside a strut [4]. In addition, a lack of proximal optimization treatment (POT)[8] may hinder crossing. Most commonly it is the distal balloon tip that limits side-branch access and if the balloon will not cross, it should be changed as it may be damaged. Rarely crossing may be limited by the width of the balloon at the zone of attachment of balloon material to the shaft where width is greater (Figure 2). This is more likely with non-compliant balloons than semi-compliant balloons and with balloons of larger nominal size because of thicker balloon material of non-compliant balloons or more balloon material with larger diameter balloons. In addition, the balloon may not cross because inflation has



**FIGURE 7** Balloon tip width at the level of attachment of balloon material for different balloon designs. For each balloon design, the width at the level of balloon material attachment (Figure 2) increases with increasing nominal balloon diameter (Figure 7). For the Sprinter and Trek designs, but not the Emerge designs, the non-compliant balloons have a wider diameter at the level of balloon attachment than the semi-compliant designs presumably because of the thicker non-compliant balloon material



**FIGURE 8** MicroCT images of a stent distorted by damaged balloon catheter tips. Twenty-five examples of 5 different stent designs were assessed. The left column shows stents damaged with side-branch access. The middle column shows the same stents after the distortion is largely corrected by mini-kissing balloon post-dilatation (Mini-KBPD). The right-most column documents the number and percentage of the 25 stents of each design that had moderate or severe distortion defined as 0.4 mm malapposition and/or 0.4 mm protrusion into the side branch after 2.5 mm Trek balloon side-branch access. The red arrows indicate a strut pushed toward side-branch. Struts upstream from the side-branch are separated (A) and those downstream are pushed together (B). There is malapposition of struts opposite the side-branch (blue arrowhead). Mini-KBPD largely corrects the malapposition aspects of distortion while retaining side-branch protrusion and ostial size (middle column)

caused balloon material “winging” in that it is no longer “wrapped” and has not returned to its pre-inflation profile.

In our clinical study and in our bench study, if the balloon failed to cross or if resistance was encountered, there was a high chance of tip damage (>80%). If crossing was successful without resistance, damage was present in almost half of balloons in the clinical study but much less frequent (3%) in the bench study. In the bench study there were not sustained attempts at crossing if the balloon did not cross easily. There is likely to be some selection bias as operators would be more likely to send us balloons from more challenging cases although balloons from sequential cases were requested.

Some balloons are more resistant to entry tip damage than others. The Flexx2 tip design of the Galant balloon is reinforced with a wire coil and is very resistant to damage but has a larger entry profile than other balloon designs (Figures 4 and 5).

We believe that some stent designs such as those with small cells (the space between struts defined by hoops and connectors) or with complicated cell shape are more difficult to cross than those with larger cells [4]. The more connectors there are between hoops, the smaller the cells and the more difficult they are to cross [4,5].

If stent damage is identified, it can be largely corrected by kissing balloon post-dilatation.

## 6 | LIMITATIONS

Our clinical study which aimed to confirm that tip damage occurs clinically with side-branch access through the side of a stent, is likely to over-estimated the occurrence of tip splaying as operators may have been more likely to send balloons for examination after difficult side-branch access.

Bench testing may not accurately predict balloon tip behavior in humans. We tested limited numbers of balloons.

Our bench bifurcation models do not have side-branch narrowing. In patients, side-branch stenosis may restrict struts being pushed into the side-branch by a damaged balloon tip.

## 7 | CONCLUSIONS

During coronary bifurcation percutaneous intervention, where a balloon catheter is required to pass through the side of a stent to the side-branch, the balloon tip is often damaged. Even when no resistance is felt with passage through the side of a stent, about half of the balloon tips were damaged. A damaged, flared balloon tip may not pass between stent struts to access the side-branch so that changing to a new unused balloon is recommended if there is failure to cross.

A damaged balloon catheter tip can cause stent distortion which can be largely repaired by kissing balloon post-dilatation.

Some balloon catheters less readily damaged than others. The Flexx2 and Trek designs were the most resistant to damage during the compression test and the Tazuna required the least force to be damaged.

## CONFLICT OF INTEREST

Trine Ø Barkholt has received a travel grant from St. Jude Medical and Biotronik. John Ormiston is an advisory board member Boston Scientific Corp and has received minor honoraria from them. Other authors report no conflicts of interest.

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