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ORIGINAL INVESTIGATION

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# Dilating and fracturing side struts of open cell stents frequently used in pediatric cardiac interventions—An in vitro study

Thomas Krasemann MD (D), FRCP | Marco N. Kruit | Arthur E. van der Mark | Martijn Zeggelaar | Michiel Dalinghaus MD | Ingrid M. van Beynum MD

Division of Cardiology, Department of Pediatrics, Sophia Kinderziekenhuis, Erasmus Medical Centre Rotterdam, Rotterdam, The Netherlands

**Correspondence**
Thomas Krasemann MD (D), FRCP, Sophia Kinderziekenhuis, Division of Cardiology, Department of Pediatrics, Erasmus Medical Centre Rotterdam, Wytemaweg 80, 3015CN Rotterdam, The Netherlands.
Email: t.krasemann@erasmusmc.nl

**Background:** Open cell stents are frequently used in interventional therapy of congenital heart disease. Overstenting of vessel branches may necessitate strut dilation.
**Methods and Results:** The strut size achievable in Bard Valeo and Cook Formula stents, and the pressure necessary to fracture struts was assessed. In addition, a self expanding stent (Optimed SinusflexDS) was also tested. With the original balloon at nominal pressure, in Valeo stents side struts could be dilated to approximately 90% of the nominal stent diameter, in Formula stents to approximately 80%. With larger high pressure woven balloons, strut size increased to approximately 125% in Valeo stents, and to approximately 105% in the Formula. Strut fracture can connect two adjoining struts. Pressures were dependent on the balloon utilized. Sidestruts of the Sinusflex could lastingly overdilated with large balloons only.
**Conclusion:** Dilation and overdilation of side struts in open cell stents can be achieved. Dependent on the clinical context, the original balloon used to place the premounted stent can be used to achieve strut dilation, but woven high pressure balloons maybe safer for patients. Should a larger diameter be required, these high pressure woven balloons can achieve bigger diameters and even strut fracture.

KEYWORDS
congenital heart disease, side struts, stent, stent fracture

## 1 | INTRODUCTION

Stents are utilized in interventional therapy of congenital heart disease since the 1980s.[1] A broad variety of stents is used to treat stenosed vessels, arteries as well as veins, and to keep created communications open (ie, interatrial stent, Fontan tunnel fenestration).[2,3]

Stents can safely be redilated according to the patient's somatic growth, but certain stents foreshorten substantially when overdilated. Dependent on the design of the stent, foreshortening can be quite extreme and dilation over a certain diameter may either not be possible without the use of extreme high pressure balloons, or lead to stent fracture.[4,5]

In pediatric cardiology, many stents originally designed for other uses, that is, peripheral vasculature, are used "off label." Stents can be categorized according to their design as closed cell or open cell. Open cell designed stents can be placed over vessel bifurcations, allowing flow through the struts into the covered vessel, while closed cell stents may jail the vessel branch.[6] There are numerous reports of dilation of these struts to allow either stents placement in the overstented vessel itself, or simply to allow better flow properties. This was first reported in the early 2000s.[7] Balloons used to achieve this vary in the literature, and little is known over the possibly achievable diameter of ballooned side struts of open cell stents.

With our study, we wanted to measure the diameter achievable with the same balloons used for stent deployment (for premounted stents), the maximum strut diameter achievable, and the diameter of two connected struts if one strut is fractured by means of ballooning. We chose two stent types frequently used in pediatric interventional practice (Valeo, BARD, Peripheral Vascular, Tempe, AZ, USA, and Formula, Cook, Bloomington, USA), and a self expanding open cell stent (Sinusflex DS, Optimed, Echjingen, Germany).

The Valeo stent is an open-cell stent with a triple helical architecture.[6] Its use in pediatric cardiac catheterization has well been documented.[6,8,9] Foreshortening during further dilating the stent seems minimal.[5,6] In one benchmark study, the struts were dilated using two 12 mm balloons side by side, and a maximum diameter of 12 mm could be achieved.[6] In clinical practice, a single balloon is usually used to achieve strut dilation, and another balloon maybe inflated within the lumen to maintain stent integrity. The Formula stent is a stainless steel hybrid cell stent with different strut sizes.[3] First reports of its use in pediatric cardiac catheterization seem positive. As the Valeo stent, it can be further dilated without much foreshortening.[3,5] We were not able to find reports about dilating the struts.

We wanted to measure the diameters of dilated struts using the original balloons on which the stents are premounted, the maximum achievable diameter and the pressure needed to fracture struts. Additionally, we tried to achieve strut overdilation in a self-expandable stent (Sinusflex DS), as this is used in pediatric cardiology with an increasing frequency, mainly to stent the arterial duct in hypoplastic left heart, where overstenting of the distal aortic arch can occur, but as well in other vessels.

## 2 | METHODS

Different sizes of premounted open cell stents (Valeo, BARD, Peripheral Vascular and Formula, Cook) were inflated to nominal diameter with the pressure advised by the manufacturers. The Cook Formula stents have a different design from the Bard Valeo, as in the former only two adjoining diamond shapes form an "open cell," while in the latter three diamonds form an "open cell" (Figure 1). An inflation device (Encore 26, Boston Scientific, Marlborough, USA) was attached to the balloon, and via a T-piece the pressure was also measured exactly with an industrial pressure-transmitter (pressure probe DRTR, B + B Thermo Technik GmbH, Donaueschingen, Germany). Once the nominal pressure was achieved, the balloon was deflated.

The same (original) balloon was then passed through the struts perpendicular to the axis of the stent, inflated to nominal pressure and then withdrawn. This position was chosen to have minimal interference of the balloon position on the achievable diameter (Figure 2). The diameter of the dilated strut was measured with a conventional micrometer. A high pressure balloon (Conquest or Atlas gold [BARD Peripheral Vascular], depending on the stent diameter) with a diameter exceeding that of the original balloon was then positioned within these dilated struts and inflated. Pressures necessary to achieve maximum dilation were measured as well as the maximally achievable diameter of the dilated struts. The maximum strut diameter was defined as the diameter at which a further increase of the balloon pressure (of the "oversized" balloon) did not enlarge the strut diameter further. The balloon (or a bigger one, if necessary) was then re-inflated with such a high pressure that the struts fractured. The pressure recordings were done continuously to document the changes in pressure during strut fracture. Then, the diameter of the two adjoining struts was measured.

In a second series (series 2), the balloon was forwarded through one side strut only and further through the lumen of the stent (Figure 2). Similarly to the previous measurements, initially the diameter achievable with the original balloon inflated to nominal pressure and the diameter of the dilated strut were measured. Second, the balloon was replaced by a high pressure balloon which was inflated to achieve maximal dilation of the strut, and then further until fracture occurred. Pressures to achieve this were recorded, and achieved diameters measured.

In addition to balloon expandable premounted stents, we also tested a self expanding stent, the SinusFlex DS, which was designed for ductal stenting in duct-dependent systemic circulation (Optimed, Ettlingen, Germany). Starting with a balloon of the same diameter as the nominal stent diameter, we dilated the struts using the nominal pressure for balloon inflation as per manufacturer's recommendation, and measured the achieved diameter once the balloon was withdrawn. With a balloon exceeding the diameter of the stent, struts were then fractured similarly to the premounted balloon expandable stents. The pressure necessary and the achieved diameter of two adjoining struts was measured.

Descriptive statistics were used. Values are presented as means and standard deviations, as appropriate. If percentages are used, these refer to the nominal stent diameter achieved by inflating the balloon expandable stents to nominal pressure, and the self expanding stent nominal diameter, as appropriate.

As no patient data were used, there was no need to approve the study by the institutional board according to the local guidelines.

## 3 | RESULTS

For the open cell stents, see Tables 1 and 2 for the achieved strut diameter, balloons, and necessary pressures.

With the original balloons, in series 1 the achieved diameter of the dilated struts of Valeo stents was smaller than the balloon diameter, 90 ± 6.3% when passing perpendicularly through the stent (series 1) and 88 ± 4.8% when passed through one strut only (series 2).

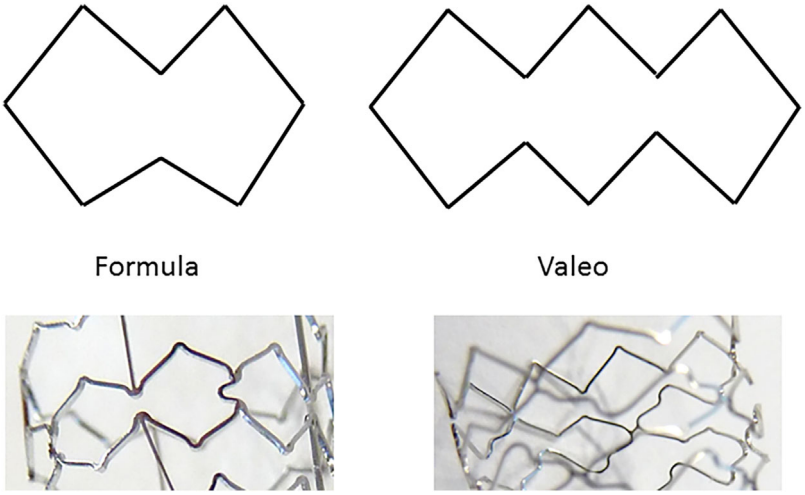


**FIGURE 1** Cell design of the Valeo and Formula stents

In the Formula stents, 77 ± 11.8% of the nominal stent diameter could be achieved with the original balloon at nominal pressure in series 1, and 95 ± 1.4% in series 2. It is noteworthy that the percentage gets smaller with increasing stent sizes in series 1.

After inflating the stents to nominal diameter, the balloons could be withdrawn from the lumen without damage and remained intact. Forwarding the original balloon through the struts without balloon damage was possible in all but one, which was the balloon of a Cook Formula with a diameter of 5 mm. Here, the balloon was punctured by the stent struts and could not be inflated. For further testing, a Cook advance balloon of the same diameter (5 mm) was then used.

Examples of the achieved results are shown in Figure 3.

To achieve the maximum diameter, relatively high pressures were necessary. Woven balloons were used. They did not fracture, but small punctures occurred. Interestingly, this did not lead to notable pressure changes (Supplementary Figure S1). The maximal achievable diameter in series 1 was 126.2 ± 4.5% of the nominal stent diameter in the Valeo, and 79 ± 10.6% in the Formula stents (Table 1). The maximal achievable diameter in series 2 was 123.5 ± 11% of the nominal stent diameter in the Valeo, and 106 ± 5.7% in the Formula stents (Table 1). Stent foreshortening occurred, but this was not measured.

Pressures needed to fracture struts were dependent on the balloon size: With larger balloon diameters, lower pressures were needed to achieve strut fracture. Interestingly, pressure changes occurring with strut fracture varied from less than one bar to two bar (Supplementary Figure S2). We could not fracture struts of any Valeo stents with 9 mm Conquest balloons, but with an Atlas Gold balloon of 12 mm diameter, we could achieve diameters of 11.2-11.8 mm of two connected struts if the struts were fractured with this balloon. In case a 22 mm balloon was used, the maximum diameter was 17 mm in the 9 × 26 mm Valeo, and the 10 mm stent on an Atlas 22 mm balloon fractured with low pressures so that no useful measurements could be achieved. Also, the lumen of the stent itself was compromised when using oversized balloons (Figure 3).

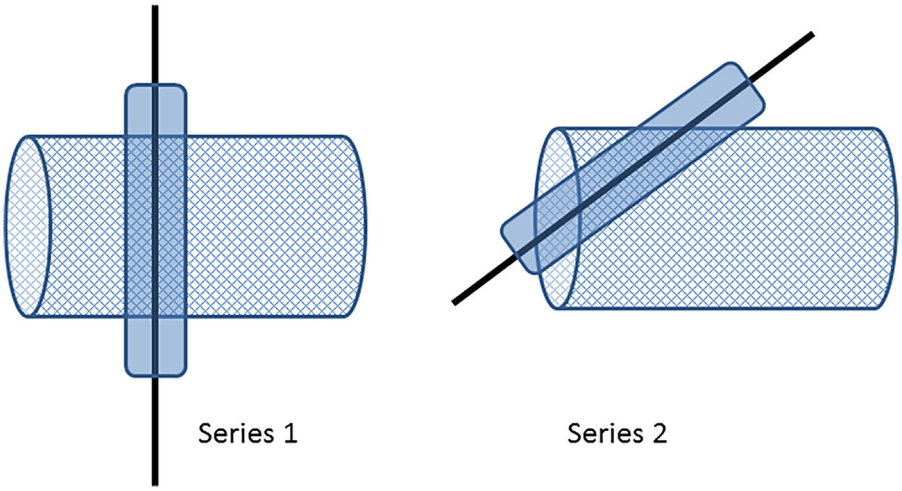


**FIGURE 2** Balloon position in series 1 and series 2

**TABLE 1** Series 1

| Stent | Size | Diameter NP | % nom diameter | Diameter max | % nom diameter | Balloon max | Pressure max | Pressure rupt | Diameter 2 struts |
|---|---|---|---|---|---|---|---|---|---|
| Valeo | 6 × 26 | 5.2 | 87 | 7.9 | 131 | Atlas Gold 12 × 40 mm | 1.1 | 7.8 | 11.6 |
| Valeo | 7 × 26 | 6.7 | 96 | 8.6 | 123 | Atlas Gold 12 × 40 mm | 4.4 | 6.9 | 11.3 |
| Valeo | 8 × 26 | 7.8 | 98 | 9.6 | 120 | Atlas Gold 12 × 40 mm | 6.3 | 7.3 | 11.8 |
| Valeo | 9 × 26 | 7.6 | 85 | 11.5 | 128 | Atlas Gold 12 × 40 mm | 16.5 | 4.5** | 17.0 |
| Valeo | 10 × 36 | 8.5 | 85 | 12.9 | 129 | Atlas Gold 22 × 40 mm | 1.9 | 4.2 | |
| Cook Formula 414 | 5 × 16 | 4.7* | 94 | 4.7 | 94 | Conquest 9 × 40 | 8.0 | 13 | |
| Cook Formula 414 | 6 × 16 | 4.4 | 73 | 4.7 | 78 | Conquest 9 × 40 | 4.9 | 9.8 | 8.3 |
| Cook Formula 535 | 8 × 12 | 5.7 | 71 | 5.7 | 71 | Conquest 9 × 40 | 25.4 | 8.8*** | 8.8 |
| Cook Formula 535 | 9 × 20 | 6.1 | 68 | 6.5 | 72 | Conquest 9 × 40 | 7.1 | 7.4*** | 8.8 |

Balloon max, balloon used to achieve maximum diameter (bar); Diameter max, maximal strut diameter (mm); Diameter NP, diameter at nominal pressure of original balloon (mm); Diameter 2 struts, diameter of two struts connected due to strut rupture (mm); Pressure max, pressure used to achieve maximum diameter (bar); Pressure rupt, pressure needed to rupture strut (bar); %nom diameter, percent of nominal stent diameter (%);.

*Original balloon ruptured. 5 mm Cook advance balloon used.

**Atlas Gold 22 mm for rupture.

***Atlas Gold 12 mm for rupture.

**TABLE 2** Series 2

| Stent | Size | Diameter NP | % nom diameter | Diameter max | % nom diameter | Balloon max | Pressure max | Pressure rupt | Diameter 2 struts |
|---|---|---|---|---|---|---|---|---|---|
| Valeo | 7 × 26 | 5.8 | 82 | 9.0 | 129 | Conquest 9 × 40 mm | 4.2 | 4.5*** | 11.3 |
| Valeo | 8 × 26 | 7.5 | 93 | 8.5 | 107 | Conquest 9 × 40 mm | 22.0 | 6.9*** | 12.2 |
| Valeo | 9 × 26 | 7.7 | 86 | 11.6 | 129 | Atlas gold 12 × 40 mm | 20.2 | 3.5** | 17.1** |
| Valeo | 10 × 36 | 9.1 | 90 | 12.9 | 129 | Atlas Gold 22 × 40 mm | 2.0 | 3.3 | |
| Cook Formula 414 | 5 × 12 | 4.7 | 94 | 5.5 | 110 | Conquest 9 × 40 | 2.3 | 8.0 | 9.1 |
| Cook Formula 414 | 6 × 12 | 5.8 | 96 | 6.1 | 102 | Conquest 9 × 40 | 9.7 | 9.8 | |

Balloon max, balloon used to achieve maximum diameter (bar); Diameter max, maximal strut diameter (mm); Diameter NP, diameter at nominal pressure of original balloon (mm); Diameter 2 struts, diameter of two struts connected due to strut rupture (mm); Pressure max, pressure used to achieve maximum diameter (bar); Pressure rupt, pressure needed to rupture strut (bar); %nom diameter, percent of nominal stent diameter (%).

**Atlas Gold 22 mm for rupture.

***Atlas Gold 12 mm for rupture.

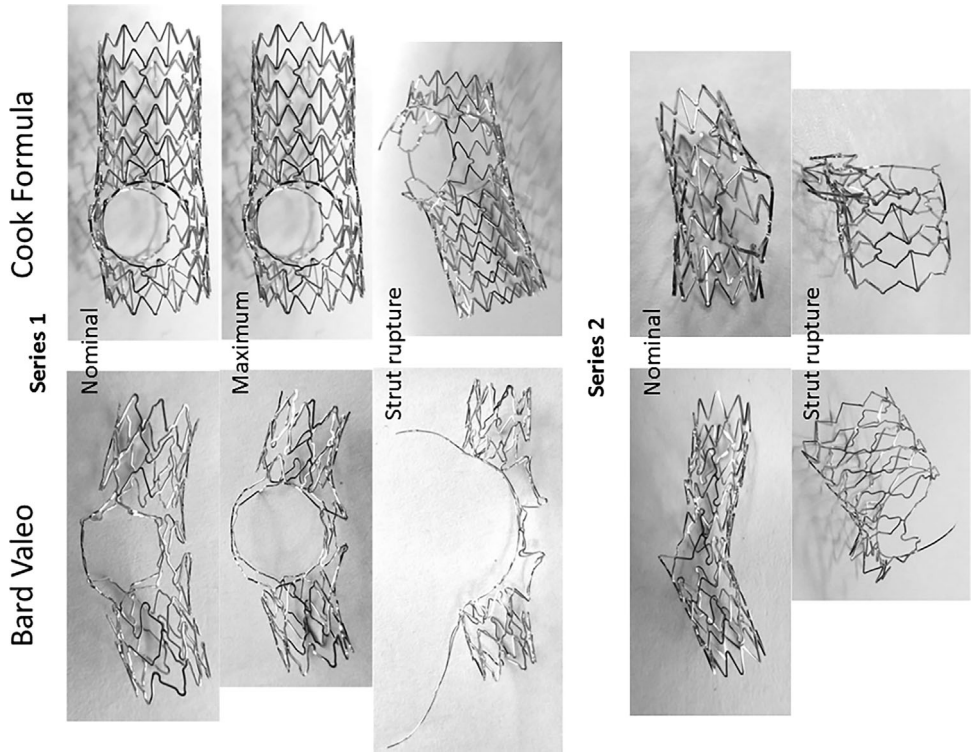


**FIGURE 3** Examples of the achieved results—maximum diameter of struts and strut fracture. Note that the maximum strut diameter in the Formula stent is the same as the diameter achieved with nominal balloon pressure

In all Formula stents, fracture could be achieved with a Conquest balloon of 9 mm diameter. The 5 mm stent lost integrity, but for all others two adjoining struts had diameters between 8.3 and 9 mm.

The struts of the self expandable 8 mm stent could be dilated with a Z-med II balloon of the same diameter as the stent (8 mm), but interestingly after initially opening of the struts, the stent recoiled to the original configuration again after approximately 5 min. With a slightly larger high pressure balloon (9 mm Conquest, Bard) the struts could be lastingly be overdilated using high pressures (12 bar). The dilated struts here were not round as in the balloon expandable stents. Fracture of a strut did not lead to further increase of the strut size, as the stent reconfigured slightly (Figure 4).

## 4 | DISCUSSION

In all balloon expandable open cell stents, we could achieve overdilation of struts easily. With the balloon provided by the manufacturer inflated to nominal pressure, the diameter of the dilated strut was in the range of approximately 80% of the nominal stent diameter in the Cook Formula and approximately 90% in the Bard Valeo stents. This seems less for the Formula stents and is dependent on the cell design—in the Formula stent, the open cells are smaller than in the Valeo (Figure 1). The maximally achievable diameter also differs, probably for the same reason. Once the struts are dilated into a circular shape (Figure 3), no further dilatation can occur as the metal itself is non-stretchable.

In clinical practice, side struts of stents will hardly ever be crossed perpendicularly as in series 1, but this approach allowed us to determine strut properties without angulations of the balloon influencing the result of the dilation. In most instances the stent will be placed in a larger vessel ("main vessel"), and may overstent a typically smaller branch (ie, the left subclavian artery in coarctation of the aorta, or branches of the pulmonary artery in patients with branch pulmonary artery stenosis). For such a situation, more than the diameter achievable with the original balloon may not be necessary. If dilation of a strut seems necessary during the implantation procedure, the original balloon may be utilized to achieve this to save equipment. On the other hand, one of the balloons (5 mm Cook Formula) was damaged during crossing the struts. Woven balloons seem to keep their integrity even when punctured.

The fact that in the Formula stents the maximum achievable diameter of a strut was bigger in series 1 than in series 2 maybe due to the oblique balloon position leading to deformation of the stents. We did not measure foreshortening of the stent itself, as we focused on strut diameters. In our in vitro series, the original balloon could be easily withdrawn from overdilated struts. This may not reflect the clinical situation, as the balloon withdrawal then is also influenced by the vessel anatomy and mechanical properties of the vessel wall. Due to bending, the balloon membrane may shear at the stent struts during ballooning or withdrawal. Hence, our findings need to be interpreted with caution. If during inflation (or withdrawal) balloon rupture occurs—which maybe not longitudinally, but radially—this may lead to

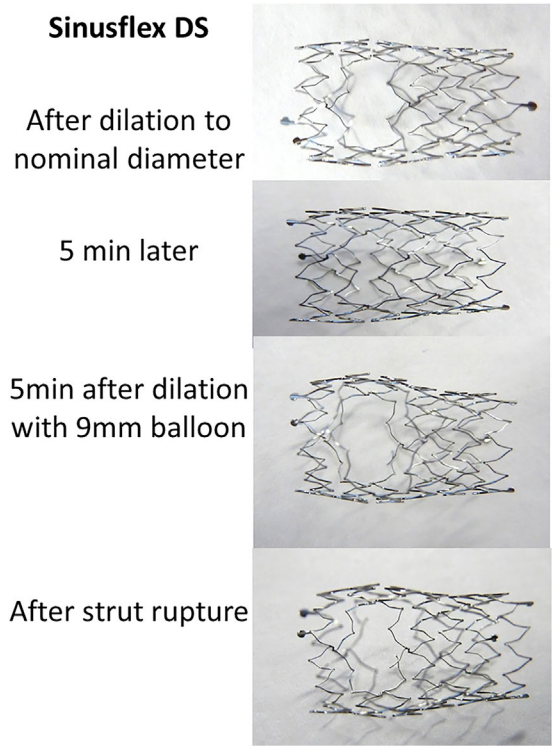


**FIGURE 4** Behavior of the self expanding Sinuspro DS stent—see text.

"parachuting" of the balloon parts, which then may make retrieval of the balloon impossible. For patient safety, woven balloons offer better security and can be recommended.

On the other hand, these woven high pressure balloons are typically less soft and have a slightly higher profile. In our series they did not fracture at all. Small punctures did not lead to relevant pressure loss. This seems to reflect clinical use, as they are frequently used not only in non-compliant lesions, but also for stent redilation or strut-dilation.[10] As the choice of high pressure balloons was limited due to availability, we could not perform a stepwise increment of balloon sizes. It may be possible that fracture can be achieved using less oversized balloons with higher pressures. We saw that larger diameter balloons fractured stents at lower pressures. In clinical practice it is unlikely that a balloon much bigger than the nominal stent diameter is used, as the target vessel in most cases will be smaller than the vessel in which the stent is implanted.

With single balloons, we could achieve large diameters of the side struts of Valeo stents, comparable to the diameter achieved by Travelli et al who used two 12 mm balloons used side by side.[6] We do not think that a double balloon technique is necessary, and may complicate a procedure further.

If over time a much larger diameter of the side strut is necessary, then struts can be fractured using high pressure woven balloons. Diameters of more than 1.5 times bigger than the diameter of the Valeo stents can be achieved. This seems more dependent on the balloon size than on the stent diameter.

In all tested Formula stents, we achieved strut fracture with 9 mm balloons, and the achieved diameter of two adjoining struts was in this range. We did not test bigger balloons, hence do not know if a slightly larger balloon would have achieved more. It is possible to overdilate further, but then the stent loses integrity. For Valeo stents, comparably bigger balloons are necessary to achieve fracture. The pressure changes that occurred during strut fracture varied. For clinical practice this means that they may not be visible immediately if pressure measurements on conventional inflation devices are used. Fluoroscopy will play a more important role to monitor progress. If high pressure balloons are used and on careful inflation on fluoroscopy the waist within the struts does not change anymore, the maximum diameter is achieved. Further inflation may lead to strut rupture. The shards may traumatize the vessel. Our in vitro study can, of course, not answer this concern.

Stent foreshortening occurred both in Valeo and Formula stents, but was not measured in our series, as it is a well known phenomenon and has been tested in vitro.[5] The struts of the self expanding stent could be overdilated, but when dilated to the diameter of the stent itself, it reconfigured within minutes. Only with high pressure and larger balloon diameter, struts could be fractured and recoil did not occur. In case a sidebranch of a vessel is overstented with this stent, one should consider stenting through the struts, as described by Kitano et al for other stents.[11]

## 5 | LIMITATIONS

We did not have all possible sizes of the tested stents available. On the other hand, the strut design is consistent throughout the models. The balloons used for testing were initially the balloons on which the stents were premounted. In clinical practice, the choice maybe different, that is, a small balloons maybe chosen first, followed by bigger ones. Anyhow, we could show that woven high pressure balloons were able to fracture stent struts, hence these balloons can be recommended if larger diameters of struts are aimed for. The range of woven balloon sizes used for testing was limited due to availability. Ideally, a catheter laboratory is equipped with all types and all sizes of balloons, but this is rarely achievable. Hence it is possible that slightly different strut diameters could have been achieved with gradual upsizing of the balloons. But as we think that the maximum achievable diameter depends more on strut design than the diameter of the oversized high pressure balloon, we accepted this limitation.

In clinical practice, balloon choice will vary dependent on the size of the adjoining vessels and the diameters aimed for. Lastly, we performed these testings in vitro and hence without supporting vessel walls. While the mechanical properties of the stents alone will be the same, they may behave differently in vivo.

## 6 | CONCLUSION

We could show in vitro that dilation and overdilation of side struts in open cell stents can be achieved. Dependent on the clinical context, the original balloon used to place the premounted stent can be used

to achieve strut dilation, but woven high pressure balloons maybe safer for patients. Should a larger diameter be required, these high pressure woven balloons can achieve larger diameters and even strut fracture.

For the self-expanding Sinusflex DS open cell stent, a balloon larger than the nominal stent diameter was necessary to achieve a lasting result. In clinical practice, where usually smaller vessels are overstented, stenting through side struts can be recommended.

### 6.1 | Impact on daily practice

Knowledge of the properties of stents will help to overdilation and fracture of sidestruts of cells in the treatment of congenital heart disease. Depending on the strut design, Valeo stent struts can be dilated to larger diameters than Formula stent struts. Self expanding stent struts have a tendency to recoil.

## ORCID

*Thomas Krasemann* http://orcid.org/0000-0003-4900-1576

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## SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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