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Letter to the Editor

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Use of BeSmooth peripheral stent in paediatric cardiology

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Abstract

I read with interest the article by Haddad et al concerning the bench testing of BeSmooth peripheral tests, and I would like to share some thoughts and highlight few points.

BeSmooth stent is behaving like any pre-mounted stent available on the market. None can achieve the Holy Grail of being dilatable to adult size without losing their integrity. Until dedicated stents are available, pre-mounted stents are preferred to unmounted stents because of their better profile and deliverability. Technically, proper post-dilatation should be performed in order to avoid and extensive foreshortening and the formation of a ring that would limit further expansion of the stent. BeSmooth stent like other pre-mounted stents can also be used without restriction in situations where overexpansion is not required.

BeSmooth stent platform with the knowledge of its intrinsic properties is, in our opinion, a good add-on to the armamentarium of pre-mounted stents used in paediatric cardiology.

I read with interest the article by Haddad et al.[1] concerning the bench testing of BeSmooth peripheral tests, and I would like to share some thoughts and highlight a few points.

No pre-mounted stents presently available on the market have been specifically designed for use in aediatric cardiology. Moreover, none of these pre-mounted stents achieved the Holy Grail of being dilatable to adult size (>22-mm). Those pre-mounted stents can be expanded from 1.3 to 2.4 times their nominal diameter without losing their physical integrity.[2] As an example, a 6-mm Formula stent will go up to 12 mm and will rupture after further dilatations.[2] Cobalt chromium stents (metal used for BeSmooth) have been shown to have more limited overexpansion properties compared to stainless steel stents but demonstrate more flexibility and strength.[3] Despite this limitation, interventional cardiologists working in the field are using those stents daily with the perfect knowledge of their limitations. There are other ways to deal with this limitation: intentional fracture of the stents being one of them (unzipping strategy). In order to achieve larger diameters when required, high/ultrahigh pressures balloons are used to damage the structure of the stent. This loss of integrity avoids fixing the diameter of the vessel and allows the insertion of a new stent that will permit further dilatations reaching the adult size. Of note, in vitro aspect of those fractures might look scary, but in vivo we have to remember that stents are completely embedded within the wall of the vessels and vascular complications have been altogether very limited. In order to achieve this goal, avoiding the creation of the so-called napkin ring is a must as breaking a ring is unpredictable and extremely difficult even with the use of ultrahigh pressures. It is a common error to think that the formation of this ring is only related to the design of the stent. The choice of the balloon for post-dilatation is crucial and explains most of the stent deformations seen in vitro and in clinical practice. Multiple studies have, indeed, shown that serial balloon dilatations of a stent with an increment of 1 or 2 mm are much better than using a single large balloon to achieve target stent diameter.[2,3] The diameter is not the only parameter to take into account. The length of the balloon is also crucial. The use of a balloon that is longer than the stent inevitably leads to forthshortening of the stent and possibly to ring formation. As described properly in the discussion section, the behaviour of the stent will be as follows: the inflation of the balloon will start from extremities to the centre. When the extremities of the balloon reach a certain diameter, the middle part will start to open up, but as soon as it reaches the diameter of the stent, the inflation will stop at this level and the extremities of the balloon will inflate to its nominal diameter. By this action, the stent will foreshorten from the extremities to the centre until the centre of the balloon opens. The extent of foreshortening is directly related to the length and diameter increment of the balloon and to a lesser extent with the design of the stent. The best way of avoiding this extensive shortening is to postdilate using a balloon that is shorter than the stent inserted and that has a diameter that is close to the nominal diameter of the stent. It is not always possible to do that, as adequate balloon length might not be available. In this case, the use of double technique balloon with two short coronary balloons is always possible. It is thus possible to reach expansion starting from the middle of the stent to the extremities before dilating with a single balloon. Using this technique, one can discriminate foreshortening related to improper post-dilatation from stent design issue. We noticed that in your study design, 4 cm balloons were used for post-dilatation of 23-mm long stents. This by

itself can explain the ring formation making the results of bench test "debatable". Of note, stents described as ideal in your paper (i.e. Valeo stents) were shown as well in vitro to go to ring configuration when post-dilated with improper balloons. Since the design of the study is being discussed, it is always better to perform a bench test that is mirroring clinical practice as much as possible. In clinical practice, the use of 58-mm long stent would be exceptional. The use of a digital (calibrated) caliper would have been more precise than the use of plastic rule that would not capture a difference of 2 mm. None of the previous bench studies have used fluoroscopy/cine acquisition to assess stent integrity. The reason is that visual inspection with the use of magnification provides a much more precise 3D assessment of stent integrity especially when dealing with open-cell-designed (or hybrid) stents. Finally, there are errors throughout the paper that needs to be modified for clarity. While test 2 described the use of 57-mm long BeSmooth stent in methods section, it is described as being 23 mm long, throughout the results section. In the table header, it is 57 mm and in the legend to figure 3 it is again written 23 mm while it appears on the figure to be a 57-mm mounted on a 4-cm long Armada balloon. The same error is repeated for Test 3 in the legend of figure 4 where the stent is being described as being 23 mm long when it seems to be 57-mm long stent assuming that Optimus stent used for the experiment was 48-mm long stent.

While the intrinsic properties of a stent are a must know for the interventionists, it is not the only parameters to take into account before using a stent in patients with CHD. Others factors like availability and indications are important to consider in order to select a stent properly. For example, it is well known in the surgical field that homografts are one the best substitutes for valve replacement. However, because of its low availability, surgeons are forced to use heterografts that are known to provide worst results in the long term. Similarly, in our field, Formula Cook stents that were the stents behaving the best (but still not perfect as far as overexpansion is considered) are presently not available in most parts of the world. Finally, we have to remember that our practice is made multiple procedures and not all of them being "curative". Defining the ideal stent as you mentioned as being the one dilatable to adult size is not appropriate. We have many indications for stenting in children where there is no need for a stent to reach adult size. Patients with a surgical "unexpandable" pathway like Sano, BT shunt, or PDA stent for hybrid approach, right ventricular outflow tract stenting, or any palliative procedure or stepwise surgery where a surgical step will be needed are some of the indications where expanding the stents to adult size is not a property that we are looking at. Properties like profile, deliverability, radial strength, and thrombogenicity would be favourable for those indications.

Dedicated stents designed to reach adult size are underdeveloped (BeGrowth/Bentley, Breakable stent/Osypka, Renata stent), but until they become commercially available, BeSmooth stent platform with the knowledge of its intrinsic properties is, in our opinion, a good add-on to the armamentarium of pre-mounted stents used in paediatric cardiology. We have been using BeSmooth stents after extensive bench test for about two years in our laboratory with very good outcome.

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Competing interests. None.

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