Byrne and Joner (1) recently wrote an elegant editorial comment on a study that our group recently published in JACC: Cardiovascular Interventions (2). We have to thank the 2 experts for their kind words regarding the importance of this type of proof of concept, independent study. However, while reading the editorial, we made several observations that may be of some help for future discussions, which we summarize in the following points:

First, despite their enthusiasm for stents, Byrne and Joner (1) should have also mentioned one of the major drawbacks of this technology, namely, the risk of very late (and never-ending) stent thrombosis. This concern has been shown to be a serious issue indeed, of very late (and never-ending) stent thrombosis. This major drawback of this technology, namely, the risk has been shown to be a serious issue indeed.

Second, we “enthusiastic adopters” of drug-coated balloons would like to underline that this technology in not “against” stents: on the contrary, it should be considered an adjunctive and complementary tool that should be available on the shelves of our catheterization labs: for example, but not exclusively, when you feel a stent is not the best choice, namely, if the vessel is too small, when avoiding jailing a major side-branch appears reasonable, or if you already have several stent layers there as a result of recurrent in-stent restenosis.

Third, we concur that the results of our study should be considered as hypothesis-generating. However, some pre-clinical data also seem to confirm that paclitaxel, given at a single-burst dose on the vessel wall, might facilitate vessel healing (3). Further studies will hopefully clarify this intriguing hypothesis.

Fourth, we fully agree with Byrne and Joner (1) that current guidelines still do not suggest drug-coated balloon use for native coronary vessels, but Byrne and Joner (1) should also mention that several expert consensus papers give clear indications for their use in this setting (4,5). We can only speculate on why the international guidelines do not reserve drug-coated balloons a role in native vessels yet. Results of several currently ongoing clinical trials are eagerly awaited to definitively answer this important question.

In conclusion, we are well aware of the limitations of our study and we concur that stronger scientific evidence is required before a change in clinical practice may be recommended. However, we strongly believe that small, independent, well-designed pilot studies are necessary to advance the field and draw the line for additional larger studies able to provide definitive clinical evidence.
Mathematics and Cardiovascular Interventions

Role of the Finite Element Modeling in Clinical Decision Making

Nowadays, mathematical and numerical models are becoming increasingly important in cardiovascular medicine. In mathematics, the finite element method (FEM) is a numerical technique used to analyze complex structures. This method subdivided a whole problem domain into simpler parts, called finite elements (FEs). Although mathematics might seem of little utility in clinical practice, several clinical reports have shown that altered flow conditions, such as flow reversal, shear stress, and flow separation, are fundamental factors in the development of arterial diseases. In this setting, the possibility to understand and predict hemodynamic alterations and long-term adaptation of the cardiovascular system, before and after surgical or interventional procedures, could be a very useful tool for surgeons and cardiologists, also for modifying their therapeutic strategies. In cardiovascular modeling, the geometric proprieties of heart and vessels are generally derived from magnetic resonance imaging, computed tomography, or angiography and then converted into the FE geometry using special commercial software. On the other hand, the material physics properties are derived from existing biomechanical studies of the tissue involved. Conventionally, computer simulation of solid and fluid structure interactions is based on the Arbitrary Lagrangian-Eulerian method. Different cardiovascular diseases have been studied via this process. Cupps et al. (1) examined the regional left ventricle wall stress in aortic regurgitation (AR) and normal systolic function, showing that it was significantly higher compared with patients with normal aortic valves. In a similar way, AR has been studied, analyzing both leaflet stress and strain (2). Computational fluid dynamic analysis (CFD) was also applied to assess the residual stress produced by ventricular volume reduction surgery, demonstrating the small post-operative effect on left ventricular function. Instead, Toeg et al. (3) focused their analysis, using the FEM, on the “ideal” biomaterial for aortic valve repair (AVr), considering that in past years, AVr has become an attractive alternative to aortic valve replacement. Similarly, Qiao et al. (4) assessed the reason of neo-aortic valve insufficiency after Ross procedure. The problem of AR due to a congenitally undersized leaflet was studied by some cardiac surgeons, who have shown that aortic root reduction can improve valve closure and eliminate regurgitation, but the result is strongly connected to both the shape and size of the resected area. Ascending thoracic aortic aneurysms were analyzed through CFD analysis which investigated aneurysm wall stress, identifying the site most prone to rupture. The mitral valve was studied by the FEM, in both normal conditions (analyzing its deformation under physiological loading conditions) and in pathological conditions. Recently, some researchers evaluated the possibility of assessing optimal mitral valve repair in a small cohort of patients using the FEM, opening the way to patient-specific optimization of surgical treatment through cardiovascular modeling. Important findings have also emerged regarding cavopulmonary shunts: the classic Norwood central shunt and the modified Blalock-Taussig procedure have been described and compared. Moreover, application of mathematical computational methods have been used as the basis for coronary angiography/computed tomography-based prediction of fractional flow reserve relative to the coronary artery lesion and for predicting coronary bifurcation adaptation to different stenting techniques (5). Multiple applications of the FEM in cardiac surgery and interventional cardiology are in the pipeline. In the near future, the FEM will be a modeling tool that will allow realization of a patient-specific approach.

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