Editorial comment: “Plug-In Hybrid”—Are we ready for this in heart valve surgery?

Torsten Doenst MD, PhD1 | Joseph Zacharias FRCS (CTh)2

1Department of Cardiothoracic Surgery, Jena University Hospital, Friedrich Schiller University, Jena, Germany
2Division of Cardiothoracic Surgery, Lancashire Cardiac Centre, Blackpool, UK

Abstract
If we think about plug-in hybrids, the treatment of paravalvular leaks in cardiac surgery may not be the first thing that comes to mind. Yet, there appears to be an attractive analogy between the plug in hybrid car and an interventional device that may be "plugged in" intra-operatively to treat a paravalvular leak. Both technologies provide additional degrees of freedom to the fields, combine different technologies but may also be criticized for their increase in cost, introduction of new problems and their questionable practical need. We address this analogy based on a case series presented in this issue of the Journal of Cardiac Surgery.

KEYWORDS
Amplatzer vascular plug, mitral annular calcification, paravalvular leak, valve repair/replacement

1 INTRODUCTION
The automobile industry has presented the combination of a combustion engine with an electric engine (hence, plug-in hybrid) as a meaningful development to meet the environmentally required need to reduce carbon dioxide emission, but still maintain the flexibility of modern mobility and avoid range anxiety. While this technical alliance may serve its purpose for specific situations, its value has been questioned for the general lack of efficiency improvement.1

Metallic occlusive devices have been developed to percutaneously occlude vessels or intracardiac openings, such as atrial or ventricular septal defects.2 These devices have then been adopted to address paravalvular leaks (PVL) in patients that have high operative risks.3 The first descriptions of such techniques date back to the early 90s.4 To address PVL in patients undergoing conventional (mostly redo) surgery, different surgical options exist for even challenging situations. In addition, some experts may argue that ample techniques exist to avoid leaks to occur during a primary valve replacement. Thus, the intra-operative use of an interventional occluder to “plug up a technical problem” (although helpful) may be considered unnecessary, similar to the plug-in hybrid car. So let us examine the topic closer.

2 PATHOPHYSIOLOGY OF PARAVALVULAR LEAKS
PVL present at the end of a classic aortic or mitral valve replacement is an unpleasant and infrequently discussed complication. The incidences of PVL amount up to 10% in the aortic position and up to 17% in the mitral position during follow-up.5–9

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.
© 2021 The Authors. Journal of Cardiac Surgery published by Wiley Periodicals LLC
PVL is often asymptomatic, but if it becomes symptomatic, its management is challenging. The guidelines provide a class I recommendation for surgery in patients with acceptable operative risk and a class IIa recommendation for a transcatheter approach in patients with prohibitive operative risk.

Mild PVL has been considered harmless until the advent of transcatheter aortic valve implantation generated large amounts of patients with mild PVL giving rise to concern regarding a potential long-term detrimental effect. Inspecting the literature carefully reveals similar associations for PVL after classic surgery.

The occurrence of PVL after classic surgery have been associated with endocarditis (a factor, i.e., relatively independent of technical aspects) and a whole series of technical factors that may or may not be avoided during the index valve replacement.

### Table 1: Factors associated with the occurrence of paravalvular leak (PVL)

- Unpledgeted sutures
- Running suture dor mitral valve
- Supraannular placement (aortic valve)
- Mechanical mitral valve prosthesis
- Size and geometric mismatch
- Lack of chordal preservation/connection to subvalvular apparatus
- Dehiscence of sutures
- Friable annular sutures
- Annular calcification

#### 3 | Technical Considerations to Avoid PVL

Table 1 shows a listing of these factors that have been associated with the occurrence of PVL either in the mitral or the aortic position. Let us examine them and our ability to avoid its occurrence.

It should be clear that using unpledgeted sutures (mainly for the aortic position) and running sutures may carry a greater risk of cutting through potentially friable tissue. This risk can easily be avoided by using pledgeted sutures, although some surgeons may argue that in small aortic annuli, the placement of pledges into the outflow tract may limit hemodynamic performance. Supraannular placement of an aortic valve prosthesis has been described as a risk factor for PVL. This may at first be surprising because a properly placed supra-annular prosthesis should be pushed onto the annulus during diastole, a mechanism which counteracts the development of PVL. However, this consideration brings us to the proper size and geometric placement of a prosthesis into an annulus (be it aortic or mitral). If the distances (e.g., from commissure to commissure or from P1 to P3, etc.) are not equally distributed along the prosthetic sewing ring, different forces may act at different parts of the sewing ring. Such geometric inconsistencies may have an impact on the development of PVL during follow up. They may also explain the occurrence of PVL in supraannular aortic position, specifically in the non-coronary position. It is conceivable that "more sewing ring" remains for "less native annulus" in the non-coronary part which is often the last area to be tied. The result is greater forces on the sutures being applied during tying and an increased risk of rupture or suture dehiscence, immediately or during follow-up. Similarly, if small prostheses in relation to the annulus are implanted, shear forces act on the sutures potentially pulling the annulus away from the sewing ring. This mechanism may explain why mechanical mitral valve prostheses have been described as risk factor for more paravalvular leaks.

An additional possible explanation may be a potentially more liberal resection of the subvalvular apparatus in mechanical valves (to avoid interference with the moving leaflets). The complete resection of all connections to the subvalvular apparatus exposes the entire mitral valve suture line to full systolic force during systole. If the continuation of chords is maintained or neo-chords to the papillary muscles are placed, forces on the annulus are likely to be eased by a parachute-type mechanism. Thus, proper sizing, preservation of subvalvular connection and appropriate geometric distribution of the annulus to the sewing ring are key factors in every valve replacement to avoid PVL.

While sutures may dehisce for improper placement or the application of inappropriate forces during tying, the tissue may be so friable in some patients that even greatest care may not be able to eliminate the occurrence of PVL. Similarly, severe annular calcification may create scenarios, where acceptance of PVL may be the better choice. Although techniques exist to deal with the most extensive forms of annular calcifications (commando-Operation, UFO operation, patch reconstruction for AV dehiscence) they may not be mastered by everyone and they may reflect too much surgery for some patients. In such cases, the "plug-in hybrid" may become handy.

Placement of an Amplatzer vascular plug generated an acceptable surgical result in all patients with only one patient presenting 1-2+ residual mitral regurgitation. Follow-up in the five surviving patients was stable without an increase in mitral regurgitation. The "plug-in hybrid" in cardiac surgery proved to be safe. This cannot be naturally expected, because if tissue fragility, large areas of calcification or the risk of suture dehiscence are the cause of the residual leak at the index replacement, the placement of these plugs may cause further calcium to break, sutures to dehisce or tissue to tear. This did not occur in the hands of the operating surgeon, who also eliminated the risk of plug dislocation by suturing the plugs to the sewing ring after placement. Thus, although not needed for the whole of cardiac surgery, the use of interventional plug devices during routine cardiac surgical procedures, such as a complex mitral valve replacement may be a safe. This approach could also be of value in minimal access surgery where calcification of the annulus has long been considered a contraindication due to the difficulty with decalcification. We could also see a role for this approach in the redo setting facilitating a less invasive approach. Thus, if you think about it, the plug-in hybrid, as many other innovative techniques that may
be heavily criticized, may turn out to be helpful enrichments of the classic surgical armamentarium.

ACKNOWLEDGMENT
Open access funding enabled and organized by Project DEAL.

CONFLICT OF INTERESTS
Joseph Zacharias receives speaker fees from Edwards Lifesciences, Cryolife, Abbott and Medtronic. Torsten Doenst has no conflict of interest to declare.

ORCID
Torsten Doenst https://orcid.org/0000-0002-6411-909X

REFERENCES
1. Plötz P, Moll C, Bieker G, et al. Real-world usage of plug-in hybrid electric vehicles: fuel consumption, electric driving, and CO2 emissions. 2020. https://theicct.org/sites/default/files/publications/PHEV-white%20paper-sept2020-0.pdf. Accessed March 19, 2021.
2. Okutucu S, Mach M, Oto A. Mitral paravalvular leak closure: transcatheter and surgical solutions. Cardiovasc Revasc Med. 2020; 21:422-431.
3. Panaich S, Raphael C, Maor E, et al. Transcatheter management of paravalvular leaks. 2017. https://www.acc.org/latest-in-cardiology/articles/2017/02/02/08/25/transcatheter-management-of-paravalvular-leaks. Accessed March 19, 2021.
4. Hourihan M, Perry SB, Mandell VS, et al. Transcatheter umbrella closure of valvular and paravalvular leaks. J Am Coll Cardiol. 1992; 20:1371-1377.
5. Dávila-Román VG, Waggoner AD, Kennard ED, et al. Prevalence and severity of paravalvular regurgitation in the artificial valve endocarditis reduction trial (AVERT) echocardiography study. J Am Coll Cardiol. 2004;44:1467-1472.
6. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH. Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. J Am Coll Cardiol. 2000;36:1152-1158.
7. Ionescu A, Fraser AG, Butchart EG. Prevalence and clinical significance of incidental paraprosthetic valvular regurgitation: a prospective study using transoesophageal echocardiography. Heart. 2003;89:1316-1321.
8. O’Rourke DJ, Palac RT, Malenka DJ, Marrin CAS, Arbuckle BE, Plehn JF. Outcome of mild periprosthetic regurgitation detected by intraoperative transesophageal echocardiography. J Am Coll Cardiol. 2001;38:163-166.
9. Ruiz CE, Hahn RT, Berrebi A, et al. Clinical trial principles and endpoint definitions for paravalvular leaks in surgical prosthesis: an expert statement. J Am Coll Cardiol. 2017;69:2067-2087.
10. Bowker LK, Price JD, Shah K, Smith SC. Characteristics and longer-term outcomes of paravalvular leak after aortic and mitral valve surgery. J Thorac Cardiovasc Surg. 2018.
11. Laakso T, Laine M, Moriyama N, et al. Impact of paravalvular regurgitation on the mid-term outcome after transcatheter and surgical aortic valve replacement. Eur J Cardiothorac Surg. 2020;58:1145-1152.
12. Eleid MF, Cabalka AK, Malouf JF, Sanon S, Hagler DJ, Rihal CS. Techniques and outcomes for the treatment of paravalvular leak. Circ Cardiovasc Interv. 2015;8:e001945.
13. Engelberger L, Schaff HV, Jamieson WRE, et al. Importance of implant technique on risk of major paravalvular leak (PVL) after St. Jude mechanical heart valve replacement: a report from the artificial valve endocarditis reduction trial (AVERT). Eur J Cardiothorac Surg. 2005;28:838-843.
14. Sameer G, Jennifer F, Stefan B, et al. A quick guide to paravalvular leak closure. Interv Cardiol. 2015;10:112-117.
15. Gafoor S, Steinberg DH, Franke J, et al. Tools and techniques—clinical: paravalvular leak closure. EuroIntervention. 2014;9:1359-1363.
16. Amorim PA, Diab M, Walther M, et al. Limitations in the assessment of prosthesis-patient mismatch. Thorac Cardiovasc Surg. 2020;68:550-556.
17. Lima B, Chamogeorgakis T, MacHanafford JC, Rafael A, Gonzalez-Stawinski GV, Lima, MD B. How to do it: the commando operation for reconstruction of the fibrous skeleton with double valve replacement. Heart Surg Forum. 2016;19:E308-E310.
18. Misfeld M, Davierwala PM, Borger MA, Bakhtiary F. The "UFO" procedure. Ann Cardiothorac Surg. 2019;8:691-698.
19. David TE, Feindel CM, Armstrong S, Sun Z. Reconstruction of the mitral anulus. A ten-year experience. J Thorac Cardiovasc Surg. 1995;110:1323-1332.

How to cite this article: Doenst T, Zacharias J. Editorial comment: “Plug-In Hybrid”—Are we ready for this in heart valve surgery? J Card Surg. 2021;36:2426-2428. https://doi.org/10.1111/jocs.15530