We appreciate the interest of Siondalski et al. [1] and his group beside numerous other international groups in working on autologous aortic valve prosthesis. We experienced tremendous interest, especially in countries where patients need a priceless and reliable bioprosthesis without the need for anticoagulation and with advantageous hemodynamics especially in the smaller sizes.

Siondalski et al. developed a prosthesis with flat leaflets. Since 1960 flat pericardium was used in aortic valve repair [2]. Our group studied the concept of a pericardial bioprosthesis with flat leaflets and performed long-term animal studies already in 2001 with a temporarily stented, autologous pericardial aortic valve prosthesis. We could demonstrate functionality of the flat pericardial prosthesis. But previous experiences in human [2] and our in-vitro experiences showed bending of the free leaflet edge in flat leaflets which can occlude the coronary ostia.

Further studies showed that coaptation area in the flat leaflet shape is reduced in comparison with a curved shape [3]. Independent of the leaflet shape, one characteristic common to this type of prosthesis is the wide opening with low transvalvular gradient. Finite element studies [3] carried out by our group could demonstrate that the forces at the commissures are reduced in curved cusps in comparison with a flat design and we studied the forces acting at such structures extensively [4].

Our objectives were: to design the prosthesis closer to the native valve which has a curved shape in closed position, to avoid free leaflet edge bending by reducing the prosthesis height, to increase leaflet coaptation area, to decrease forces acting at the commissures by forming a cusp shape, and to simplify and expedite the construction and implantation process of the prosthesis by using single point attached commissures (SPAC).

We developed the concept SPAC in autologous pericardial aortic prosthesis with a curved shape and low profile resembling the native valve shape.

The design went through rigorous engineering investigations, including computational finite element analyses and in-vitro testings, comparing it with various valve mold geometries. Long-term animal studies [5] demonstrated safety and efficacy of the final design of a molded SPAC valve prosthesis with reliable competence, exceptionally low transvalvular gradient and no free leaflet edge bending.

We shared the concerns about the connection between the leaflet-commissure and the aortic wall. In our studies we found the aortic wall to be the weakest structure that needs to be supported [4]. Changing the prosthesis design does not help the condition of the aorta; also adding T-shaped laps at the leaflet commissures does not prevent the sutures from cutting through the aortic wall but makes implantation more difficult. We found that simply reinforcing the commissural sutures with a pericardial pledget outside of the aortic wall will provide a safe anchor for the commissures. In our long-term animal studies we used only one suture at each commissure to prove the safety of the SPAC [5]. Concerns about using only a single suture can be overcome by simply placing more than one suture in a line down from the commissural point.

References


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Letter to the Editor

Radial artery versus saphenous vein as a second coronary bypass conduit in septuagenarians

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The recent article by Hayward and colleagues [1] reported mid-to-late RAPCO trial survival in septuagenarians. They found that patients who receive an internal-thoracic artery to the left anterior descending (LITA-LAD) had similar 10-year survival when the next best target is grafted with radial artery (RA) or saphenous vein (SVG). This result diverges from those in a related retrospective propensity-matched analysis where RA and SVG were compared as the second conduit of choice in LITA-LAD CABG [2]. There, RA was associated with significantly improved 6-year survival particularly after the third postoperative year, and this was true for both the younger and older sub-cohorts [2]. These discordant findings [1,2] may derive from more restrictive inclusion/exclusion criteria of the RAPCO trial [1] compared to a large all-inclusive retrospective series. We wish to communicate a number of observations that may elucidate further these divergent findings:

(i) The RA and SVG PAPCO groups’ number of grafts was similar at 3.2 and 3.3 grafts [1] yet no information on arterial versus venous use for the third and fourth grafts is given. The authors are leaders of RA use and given their propensity to maximize arterial grafts, it is likely...
that the total arterial grafts were similar for the SVG and RA groups. If true, this may explain the similar survival data. Multiple groups have reported that increasing arterial grafts results in improved survival.

(II) It is safe to assume that most to all patients had multi-vessel coronary disease. But, it is conceivable that the two- versus three-vessel disease may have differed for the study groups (data not provided), providing this serves as a surrogate measure of completeness of revascularization, a well-accepted determinant of mid-to-late CABG outcomes.

(III) The authors’ primary criterion for the 'next best target other than the LAD' for study conduit placement was the coronary target vessel size. Hence, because of the usual greater probability of right coronary dominance, it is quite likely that a disproportionately higher number of the study conduits (SVG or RA) may have been used to revascularize right coronary artery (RCA) targets as opposed to LAD diagonals or branches of the circumflex system. Ironically, multiple authors have reported that RA graft patency is generally worse when placed to the RCA even when >70% stenosis is present (e.g., [2,3]). Critically, this considered with point II above, puts forth the possibility that the SVG group may have had more radial grafts placed to targets where it is associated with superior patency when compared to the RA group. Such a scenario has significant implications on the survival comparison, and a more complete description of the overall RA and SVG graft placement is needed to allow a better interpretation of this study’s findings.

(IV) We noted that RA had a larger number of protocol breaches compared to SVG (9 vs 2) that are uncorrected given the intent-to-treat analysis. Given the small sample size and low overall adverse events rate, it is helpful if a description of these events in breaches (if any) is provided, or if a complementary comparison with breaches removed is shown.

We congratulate the authors on this thought-provoking paper and look forward to their response.

References


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Reply to the Letter to the Editor

Reply to Zacharias and Habib

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The authors thank Habib and Zacharias for their interest in our recent report of mid-term clinical outcomes in one arm of the Radial Artery Patency and Clinical Outcomes study [1,2]. They note some differences in the finding of this study when compared with their own findings reported in Circulation in 2004. The latter was, however, a retrospective analysis of propensity-matched pairs whereas we have reported the findings of a carefully conducted randomised controlled trial, which we regard as the gold standard test. They attribute some discordance in the findings of our two groups to more restrictive inclusion or exclusion criteria in our trial compared with their ‘all inclusive’ retrospective series, but we would argue that such a retrospective analysis is inclusive by design and therefore contains a degree of bias which an RCT avoids by the appropriate use of exclusion criteria.

The first question concerns the conduits used for third or fourth order grafts, based on the supposition that as proponents of arterial grafting, we would have favoured a total arterial strategy in those patients randomised to receive a radial artery for the study graft. In fact, this supposition is incorrect: patients randomised to a radial artery received 8 radial arteries and 122 saphenous veins for their third or fourth order grafts, with only 5 patients in total receiving a non-study arterial graft. Of those randomised to saphenous veins, 11 patients received a non-study arterial graft, with a total of 122 saphenous veins and 13 radial arteries used for third or fourth order grafts. Thus, there is a non-significant trend to greater use of arterial conduits in patients randomised to receive a saphenous vein for the study graft, the reverse of that which is suggested by our correspondents.

The second question relates to the distribution of two- vs three-vessel disease in the two groups. The mean number of grafts per patient is similar at 3.2 vs 3.3 grafts per patient in each group. In the radial group, 22 patients had two-vessel disease and 93 had at least triple-vessel disease (receiving 3–7 grafts). In those randomised to saphenous vein, 10 patients had two-vessel disease and 102 had triple-vessel disease requiring 3–5 grafts. Thus, there is no significant difference in the proportion of patients with only two-vessel disease in each group.

The third point made Habib and Zacharias presupposes that because right coronary dominance will be found in the majority of patients, the largest proportion of study grafts...