

32. Englum BR, Pavlisko EN, Mack MC, Ganapathi AM, Schechter MA, Hanna JM, et al. Pseudoaneurysm formation after Medtronic freestyle porcine aortic bio-prosthesis implantation: a word of caution. *Ann Thorac Surg.* 2014;98:2061-7.

Key Words: aortic valve surgery, xenografts, homografts, survival

Discussion



Dr Neal D. Kon (*Winston-Salem, NC*). I congratulate Dr Melina and colleagues on an outstanding study with superb results. In particular, I would like to praise the dedication and commitment they have shown in completing a randomized trial and following each group for 20 years.

The results are outstanding. The patients at our center have enjoyed the benefits of both these natural valves implanted as root replacements since 1992. This is when we started implanting the Freestyle as part of the initial worldwide study. Unfortunately, we have not shown the same commitment to following these patients long-term.

Stentless valves have been abandoned by many surgeons despite their optimal hemodynamics and superior durability. There are a host of reasons why other surgeons have not adopted stentless valves using a full root technique. First, it's technically more challenging to implant than the standard stented valve; second, studies in the literature show higher mortality when doing a root replacement compared to stented valves. Studies also suggest poor durability of stentless valves when using a subcoronary technique, although you had not used the subcoronary technique in your study. For many surgeons, they have encountered coronary artery reimplantation challenges. There are also articles in the literature that describe pseudoaneurysm formation in Freestyle roots, both in the sinuses and beneath the valve. I have also heard many surgeons complain about how challenging a redo operation is with a previously implanted homograft or Freestyle root.

Could you address each of the issues I just described in your series, whether or not you have encountered any of these problems, and what you have done to address them?

Second, you must have an outstanding approach to redo root replacement with homografts and Freestyles. Could you share with us some of the pearls that you might have developed over the years for doing redo root replacements?

I also can't help but ask you if you have used TAVR in any redo stentless valves or homografts, and if so, some people say that's more difficult. So could you share with us some pearls with regard to that.



Dr Giovanni Melina (*London, United Kingdom*). The main reason why these results are interesting is because we had the opportunity to see these patients constantly, and this thanks to Professor Yacoub, who left us with a legacy to follow them up.

To answer your questions, yes, technically a full root replacement is more challenging than a standard stented valve and should be done by experienced aortic surgeons, but once learned, including careful coronary mobilization and reimplantation, it becomes a routine operation. In particular in case of Freestyle implantation, there is no need to rotate the valve, only a nice hole in the right position to avoid tension or torsion or kinking of the proximal coronary artery, and it is done. Pseudoaneurysm formation has never been an issue in the present series or in any other Freestyle implantation outside this study.

Regarding the higher mortality, if one looks at the early mortality rate for this study, for isolated root replacement this was only 1%, 0% in the Freestyle and 2.5% in the homograft recipients, which is not worse than any other routine aortic valve replacement.

Regarding durability, I fully agree with your observation. No subcoronary implantations have been performed, and we believe that this could be one of the reasons for the good results for these valves over a true long follow-up, which compares well with other commercially available counterparts. Redos for these patients, like any other redo, are challenging, I agree.

Indeed, the root at reoperation is often a bunch of calcium, but once you have carefully removed it, you have a skeletonized root, which you can easily replace and the native coronary ostia are always free of calcium.

Finally, 3 patients underwent TAVI. I am not a TAVI surgeon, but it is known that this procedure with the Freestyle is more challenging because of the absence of a stent, probably the same for homografts. However, it was possible with success in all of them, and they did well.



Dr Joseph E. Bavaria (*Philadelphia, Pa*). This was a beautiful study and is a nice update from the midterm and early studies that were previously reported. I tend to agree completely with the results, especially the comments about the fact that the Freestyle is as good and probably better than a homograft, and I think that's the reason why we have adopted the full root Freestyle.

I am a disciple of Dr Kon regarding the full root implantation and stopped doing subcoronary implants after about 20 and have done 400 to 500 of the full-root Freestyles.

We have used TAVI, and it's okay, but what's really nice is the sutureless valves are a really good indication for this.

My question to you is about failure modes. It seems to me looking at our large series of homografts and Freestyles, which we started in 1997, is that the homografts tend to fail a little slower than the Freestyles. The Freestyles are fantastic, and then when they start to fail with aortic insufficiency, they fail within 6 months, whereas the homografts, just like you showed, there are a lot of them that have 2 or 3+ aortic insufficiency for a little while and then they finally just fall off the cliff. Can you just describe for me what your experience is in your center, which is the original center, for the failure modes?

Dr Melina. The main failure mode for the Freestyles is calcification of the aortic root wall. In the homografts, there is calcification of both the root and the leaflets.

Dr Bavaria. A quick follow-up question. I will put you on the spot. In your experience after all these years, is there any bioprosthetic valve that lasts as long as a Freestyle full root?

Dr Melina. As a full root?

Dr Bavaria. Is there any bioprosthetic aortic valve that lasts as long as the Freestyle full root?

Dr Melina. We have shown excellent long-term results for the Freestyle bioprosthesis with survival curves comparable to the sex- and age-matched UK population. To answer your question, only a prospective randomized trial designed to compare different prostheses, as we did here for Freestyle and homograft roots, will clarify which one performs better, especially in the long-term.