Editorial Commentary

Durability of the Starr-Edwards Heart Valve:

Early Decisions Led to Successful Results

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We welcome the opportunity to comment on Yalcinkaya and colleagues' report of a Starr-Edwards (SE) mitral valve that is still functioning after 41 years.[1] We too have some long-lived SE valve patients in our own historical follow-up records, which we established over 50 years ago, beginning with the first patient in whom we implanted the valve. As of November 2015, our longest-lived survivor has had her original ball-valve prosthesis in the aortic position for 51.7 years (more than 2 billion heartbeats), and our longest-functioning mitral valve has lasted for 44.4 years.

We are gratified, but not surprised, by the durable results from the SE ball valve. Durability was a major design consideration during its development.[2] We were concerned that the "artificial" nature of the valve would cause a constant fear that the valve might fail. Lowell Edwards, the co-inventor (Fig. 1), made it his mission to seek the optimal design and materials to ensure durability and thereby minimize this potential psychological burden on the patients. Our goal was to build a life-supporting prosthesis that would last for a lifetime.

Design

We tried many designs (including a bileaflet valve) and decided on a caged-ball design for these reasons:

- There is no hinge—the occluding component (ball) is not attached to the cage, and in fact moves completely away from it, minimizing blood cell damage and clot formation;
- The ball rotates randomly in 3 dimensions, thereby distributing wear uniformly; and
- The lubricity of blood was measured by Edwards, and he determined it to be satisfactory to cushion and protect the valve components.

Materials

Our selection of materials was carefully predicated on evidence and close cooperation with suppliers to ensure the best performance of the valve, including optimization of the materials and the manufacturing techniques. The chosen materials all had histories of biocompatibility in medical implants:

- Stellite, for the cage, was used in orthopedic implants;
- Silastic, for the ball, was used in implanted conduits; and
- Dacron, for the sewing ring, was used in implanted patches.

The sewing ring was heavily cushioned to ensure coaptation in irregular annuli, to prevent leakage. An added feature was the quietness of the SE valve in comparison with subsequent mechanical heart valves.

In the early years, feedback from surgeons and patient experience resulted in rapid fine-tuning of the design and manufacturing process. The mitral valve went through 8 minor modifications from 1960 to 1965 as the original prototype evolved into the Model 6120 mitral valve, which was then unchanged until business decisions caused discontinuation of its production in 2004. We believe this to be the only high-tech medical device to have been used continuously, unchanged, for 40 years.

The Human Element

Looking back, more than 50 years later (Fig. 2), we have not observed the anticipated negative psychological impact on our patients. In fact, we had the privilege

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to witness, time and again, the gratitude and love that our patients expressed for this artificial device that was keeping them alive. The amazing durability of the SE valve was a source of psychological *security* for our patients—among them, no doubt, the 41-year mitral valve recipient described in Yalcinkaya and colleagues' case report.[1]

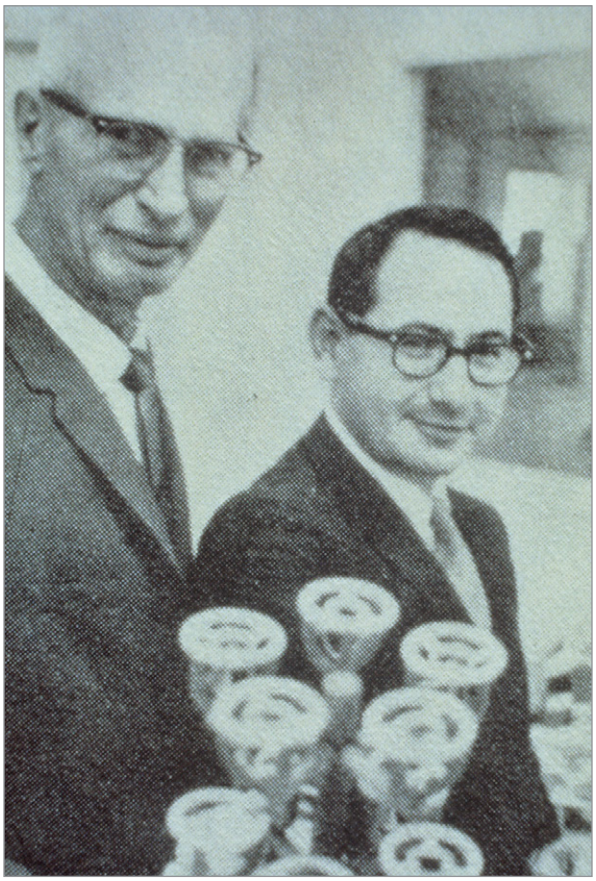

Fig. 1 *Mr. Lowell Edwards (left) and Dr. Albert Starr with caged-ball valve molds, ca. early 1960s.*

Fig. 2 *From right to left, Dr. Albert Starr and his statistical colleagues, Dr. YingXing Wu and Dr. Gary L. Grunkemeier (2006).*

References

1. Yalcinkaya A, Diken AI, Dogan T, Memic K, Yilmaz S, Cagli K. Starr-Edwards caged-ball valve: still working after 41 years. Tex Heart Inst J 2016;43(1):96-7.
2. Matthews AM. The development of the Starr-Edwards heart valve. Tex Heart Inst J 1998;25(4):282-93.