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The Caged-Ball Prosthesis 60 Years Later: A Historical Review of a Cardiac Surgery Milestone

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Sixty years ago, 2 cardiac operations dramatically influenced the survival of patients with valvular heart disease. The replacement of an aortic valve by Dwight Harken and of a mitral valve by Albert Starr with mechanical caged-ball valves, both in 1960, was a true milestone in the history of cardiac surgery and the beginning of a long journey toward prosthetic valve replacement full of expectations, hopes, and dreams fulfilled. Caged-ball prostheses underwent numerous modifications in design and materials to improve reliability and prevent specific mechanical and thrombogenic complications. Clinical and pathologic experience gained during the past 6 decades has enabled the development of safe, durable, and minimally thrombogenic mechanical prostheses. ***(Tex Heart Inst J 2022;49(2):e207267)***

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Just over 60 years ago, 2 historic operations performed within months of each other dramatically changed the survival outlook for patients with valvular heart disease. In March 1960, Dwight Harken performed the first aortic valve replacement (AVR); in September, Albert Starr performed the first mitral valve replacement (MVR).[1,2] The native valve in each case was replaced with a caged-ball mechanical prosthesis. So began the era of valvular surgery, which until then had been confined to attempts to relieve mitral stenosis by closed commissurotomy.[3] In this review, we trace the long journey from the first caged-ball valves to today's mechanical valves of various designs and materials.

Prologue

In 1951, Charles Hufnagel conceived a mechanical ball-valve based on a bottle stopper patented almost a century before.[4,5] Hufnagel's valve consisted of an inlet, an outlet, and between them a chamber containing a ball. Initially, the entire prosthesis was made of polymethyl methacrylate (Lucite); to reduce noise, Hufnagel later replaced the Lucite ball with a hollow, silicone rubber–covered ball. Hufnagel's goal was to develop a prosthetic valve that would treat aortic insufficiency while functioning satisfactorily within the cardiovascular system.[6] At the time, certain cardiac operations were done only on a beating heart under generally mild hypothermia or with use of cross-circulation as pioneered by C. Walton Lillehei.[7] Introduction of the heart-lung machine, which would make cardiopulmonary bypass (CPB) possible, was still one year away.[8] Repair or replacement of the ascending aorta had not yet been demonstrated. Others, however, had shown that the thoracic aorta could be temporarily and safely clamped during aortic coarctation repair.[9,10] In 1952, Hufnagel decided to implant his device with a sutureless fixation ring in the descending aorta of a 30-year-old woman who had aortic valve insufficiency.[4]

Functionally, the Hufnagel ball valve did not replace the AV, but assisted it by eliminating most aortic regurgitation. Many recipients of the valve showed short- and long-term clinical improvement.[7] In 1975, Fishbein and Roberts reviewed postoperative outcomes in 55 Hufnagel valve recipients, and observed that most deaths were unrelated to valvular dysfunction.[11] They concluded that the device could remain in place even if the AV itself were replaced.[11] Eventually, more than 200 patients received the Hufnagel prosthesis.[12] The caged-ball concept was ready for development.

Caged-Ball Prostheses

Harken-Soroff Valve (1960)

In the first AVR, Harken implanted in the subcoronary position a prosthesis consisting of a stainless-steel double cage containing a silicone ball and an Ivalon (polyvinyl acetate) patch (Fig. 1).[12] The outer cage of the Harken-Soroff valve was designed to keep the ball from impinging on the aortic wall and possibly causing valve malfunction. Harken performed his AVR through a bilateral throracotomy with the patient under CPB, with cooling to 26 °C and left ventricular decompression through the left atrial auricle. A modified longitudinal aortotomy exposed the native AV for replacement with the prosthesis. Only one of the first 5 recipients of the Harken-Soroff valve survived.[1] The valve was used in fewer than 20 patients and was soon abandoned.

Starr-Edwards Valve (1960)

The first Starr-Edwards prosthesis, intended for MVR, consisted of a Lucite cage, a silicone rubber (Silastic) ball, and a Teflon sewing ring.[13] The valve failure rate in canine experiments was high, mainly because of valvular thrombosis.[14] Numerous design modifications followed.[15] Adding a Silastic shield to cover the valve suture line substantially reduced thrombus formation after MVR in dogs.[16] Nevertheless, Starr used his original design in the first successful MVR, in a 33-year-old woman.[2] This model was soon replaced by one comprising a metallic cage made of a cobalt-chromium-molybdenum-nickel alloy (Stellite), a Silastic ball, and a silicone rubber sponge in the sewing ring.[12] Later models were even less thrombogenic. Model 6120 had a cloth-covered inflow face and thinner cage struts. Model 6300 had an entirely cloth-covered cage and a hollow Stellite ball.

The aortic Starr-Edwards prostheses evolved in a similar way. A prototype designed with a 4-strut stainless-steel cage and a silicone ball was followed by 3-strut cage[12] and cloth-covered versions.

Despite their reduced thrombogenicity, the Starr-Edwards valves soon began to show increasingly frequent wear on cloth-covered orifices and struts.[17,18] This problem was dealt with in a new series of "track valves" consisting of an outer cage covered in thin polypropylene cloth and an inner cage with narrow bare metallic tracks meant to prevent contact between ball and fabric. Another frequent problem with early Starr-Edwards valves was ball variance, changes in ball size caused by physical and chemical alterations in the silicone.[19] In models manufactured up to 1965, lipid absorption and swelling led to ball grooving and fragmentation from contact with the cage and the possibility of embolization.[19] Curing the silicone rubber and heating the ball at high temperature before placing it in the cage resolved the problem.[20]

Worldwide, perhaps 175,000 or more Starr-Edwards prostheses were implanted until production ceased in the early 2000s (Fig. 2).[13,21,22] The device has proved extremely durable, lasting as long as 44 years after AVR and 51 years after MVR.[21-25]

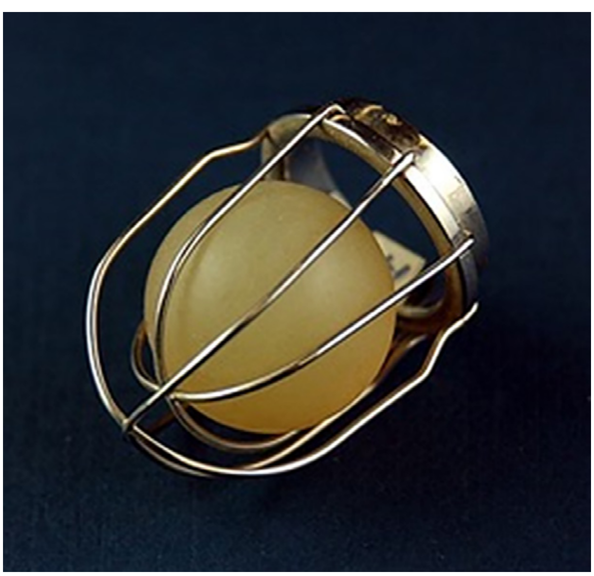

Fig. 1 *Photograph shows a Harken-Soroff valve with a stainless-steel double cage and silicone ball.*

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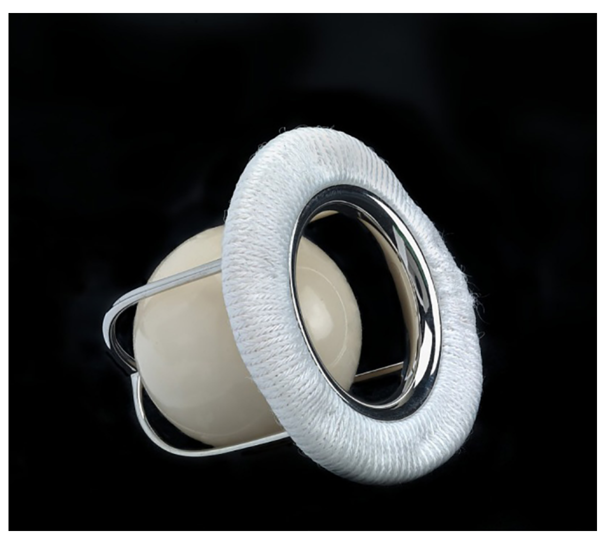

Fig. 2 *Photograph shows a Starr-Edwards valve, with a Stellite cage and a Silastic ball.*

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Pemco-Cartwright Valve (1961)

Introduced in 1961, the Pemco-Cartwright valve consisted of a 6-strut closed cage (later changed to an incomplete 4-strut cage), a Teflon-covered sewing ring, and a heat-cured Silastic ball (Fig. 3).[26,27] Little clinical information about this valve is available in the literature, suggesting that few were ever implanted. In 1961, the valve was used for combined AVR-MVR in a patient who survived approximately 4.5 months with excellent hemodynamic results.[26] In 1991, the Pemco-Cartwright prosthesis was mentioned by Akins in a review of mechanical prostheses.[28] That same year, a report from the University of Padua, describing cases of acute failure of various mechanical prostheses because of thrombosis and fibrous pannus formation, included mention of thrombosis in a patient after AVR with use of a Pemco-Cartwright prosthesis.[29] Ball variance was also problematic in this valve (Fig. 4).

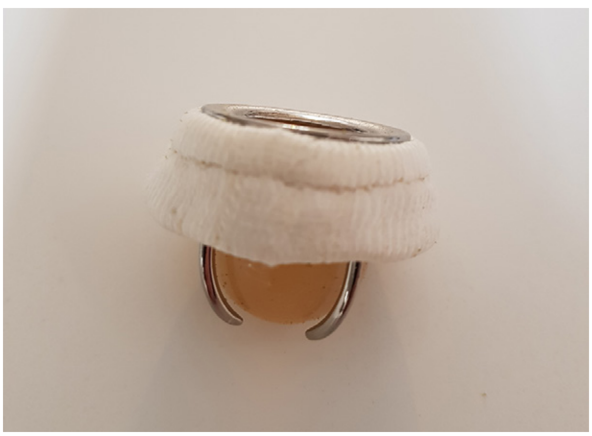

Fig. 3 *Photograph shows a Pemco-Cartwright valve, with an incomplete 4-strut cage and a Silastic ball.*

Fig. 4 *Photograph shows ball variance due to lipid absorption by the ball of a Pemco-Cartwright valve.*

Magovern-Cromie Valve (1962)

Early in the caged-ball valve era, prosthetic valve replacement was considered extremely risky because of the technical problems associated with valve insertion and the need for prolonged CPB, which increased the risk of myocardial ischemia. The Magovern-Cromie valve, introduced in 1962, was designed to overcome these problems. The prototype consisted of a closed stainless-steel cage, a silicone ball, and a unique, rotatable inner basal ring containing 9 titanium pins for fixation (Fig. 5). That unique feature made possible quick, sutureless implantation. The prototype was subsequently modified to include an open titanium cage and a radiopaque ball. Although production ceased in 1980, the Magovern-Cromie valve continued to be used and had favorable 25-year results.[15,30] Of note, the concept of sutureless fixation, which Hufnagel had already attempted and which was applied in the Magovern-Cromie valve, would be revitalized and successfully applied to bioprosthetic AVs 50 years later.[31]

Smeloff-Cutter Valve (1966)

The Smeloff-Cutter prosthesis, introduced commercially in 1966, had a unique double-caged design very different from that of the Harken-Soroff valve (Fig. 6).[32] It consisted of a double open cage of bare titanium and a silicone rubber ball. The clearance between cage and ball was designed to produce an antithrombotic washing effect. The valve's reduced height limited its protrusion into the left ventricle during MVR; its smaller ball reduced the risk of aortic wall contact and the consequent prosthetic stenosis that had been observed with the Starr-Edwards valve.[32] Nevertheless, ball variance led to the use of cured silicone balls in subsequent models. Despite the valve's allegedly superior hemodynamic performance and ability to be used without

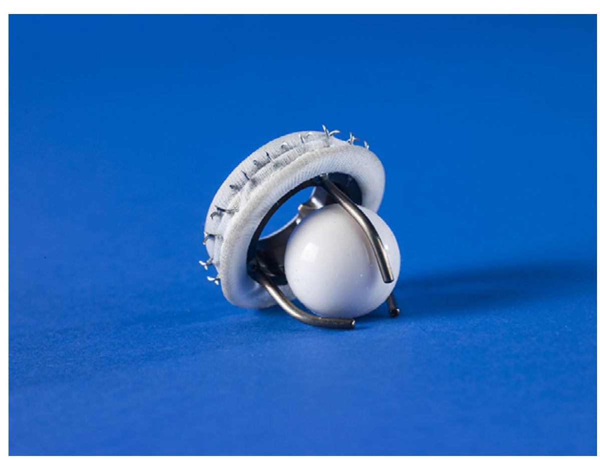

Fig. 5 *Photograph shows a Magovern-Cromie valve, with a stainless-steel cage, a silicone ball, and a sutureless fixation ring.*

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anticoagulation therapy,[33] its open cage was in several cases considered responsible for endocardial perforation by the strut tips and entanglement of the struts in papillary muscle remnants during MVR.[14,34] Although the Smeloff-Cutter prosthesis was used clinically until the late 1980s,[15] data on long-term outcomes are lacking. However, there are individual reports of Smeloff-Cutter valves that were still functioning 43 years after MVR and 49 years after AVR.[35,36] A combined total of approximately 72,000 of the valves were implanted in the aortic and mitral positions.[15]

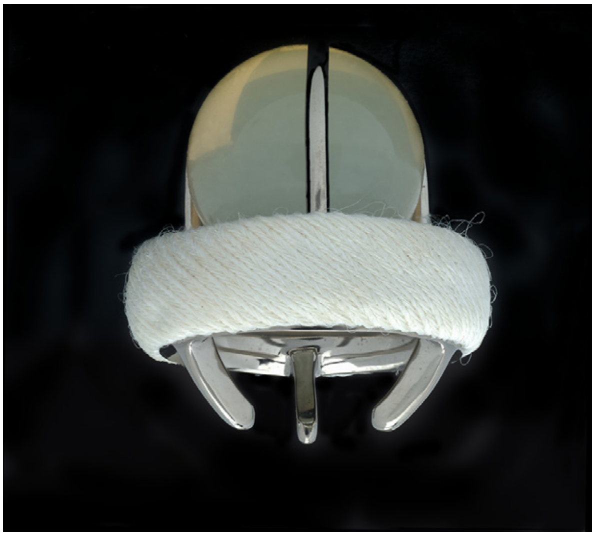

Fig. 6 *Photograph shows a Smeloff-Cutter valve, with a titanium double open cage and a silicone rubber ball.*

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DeBakey-Surgitool Valve (1967)

The DeBakey-Surgitool valve had a closed caged-ball design that for the first time incorporated pyrolytic carbon, an extremely strong, thromboresistant, biocompatible material (Fig. 7).[37] The substance comprised the valve's hollow plastic ball and covered its 3 bare titanium struts.[37] The valve's plastic, polyethylene sewing ring was intended to prevent endothelial covering and avoid leakage during diastole. A major issue with this valve was strut wear and rupture due to repeated contact of the harder pyrolytic carbon ball with the softer titanium cage, leading in some cases to ball embolization (Fig. 8).[11] Nevertheless, extended durability of greater than 30 years has been reported.[38] An estimated 1,200 DeBakey-Surgitool prostheses were implanted in the aortic position until 1984, when production ceased.[15]

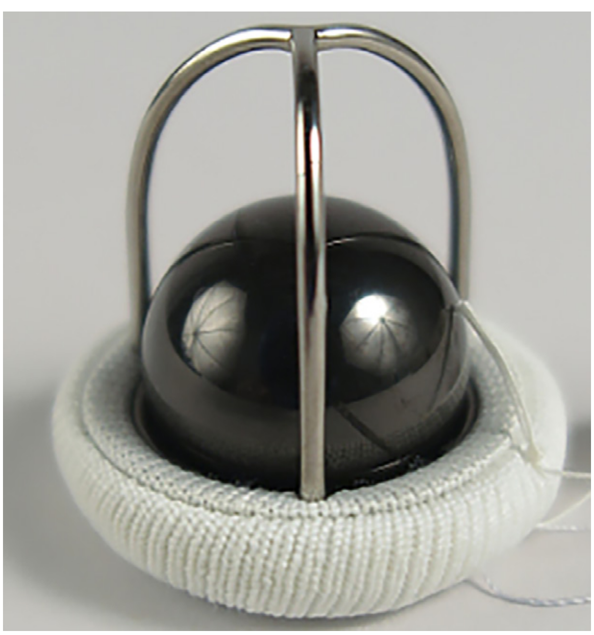

Fig. 7 *Photograph shows a DeBakey-Surgitool valve, with a titanium cage and a hollow pyrolytic carbon ball.*

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Braunwald-Cutter Valve (1968)

The Braunwald-Cutter device had an open titanium cage with 3 Dacron-covered struts, an orifice covered

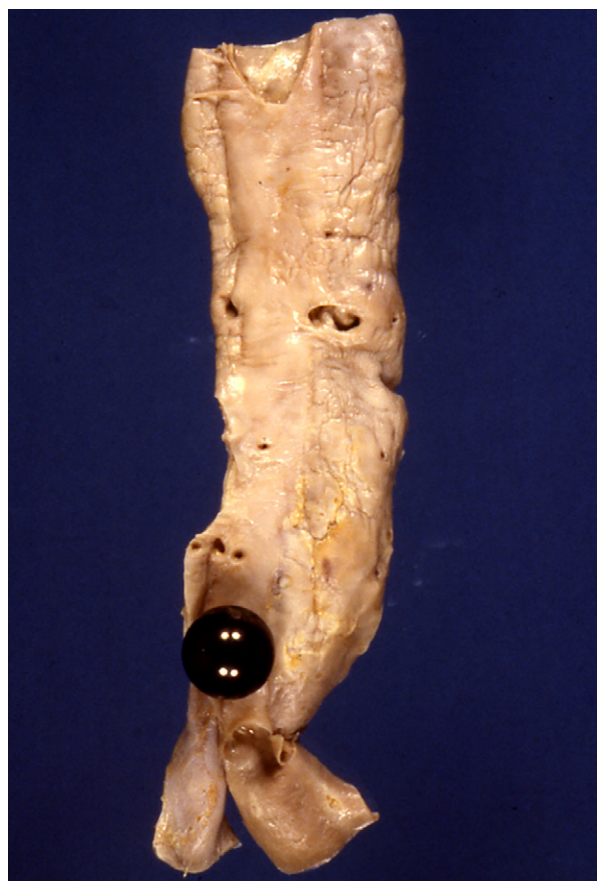

Fig. 8 *Photograph shows a fatal embolism of the ball of a DeBakey-Surgitool valve after cage rupture. On gross examination, the ball was found at the aortic bifurcation.*

by an ultrathin polypropylene mesh, and a silicone rubber ball (Fig. 9). The extensive use of cloth coverings was the result of continuing efforts to reduce thrombogenicity by promoting growth of thin layers of autologous tissue.[39] Laboratory findings had indicated that thrombogenicity was influenced by the type, geometry, and thickness of the cloth used.[39] The Braunwald-Cutter valve was first implanted clinically in 1968. Early results were encouraging, despite a series of postoperative prosthesis-related complications including ball escape and strut cloth wear.[40,41] Approximately 5,000 Braunwald-Cutter prostheses were implanted, until production ceased in 1979.[40,41] In isolated cases, the valve has functioned beyond 40 years.[42]

Conclusion

The most popular caged-ball prostheses were safe, durable, and minimally thrombogenic, the result of 6 decades of efforts to identify and optimize materials and to understand and correct problems in design and function. Cage and ball wear were mitigated by incorporating materials that reduced erosion of either component by the other. The risk of thromboembolism, a major drawback of all caged-ball prostheses necessitating lifelong anticoagulation, was greatly attenuated by improvements in design, biocompatibility, and hemodynamic performance. Meanwhile, knowing the characteristics and peculiarities of these durable prostheses remains important, because many recipients still survive. After 60 years, the caged-ball valve continues to benefit new generations through the history of its development and the extremely reliable cardiac valve substitutes that have resulted.

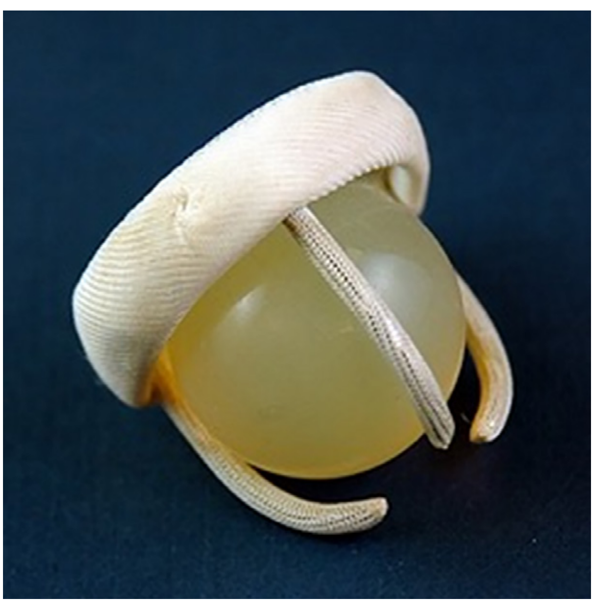

Fig. 9 *Photograph shows a Braunwald-Cutter valve, with an open, Dacron-covered titanium cage and a silicone rubber ball.*

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