

## MORE THAN TEN YEARS' EXPERIENCE WITH THE BJÖRK-SHILEY TILTING DISC VALVE

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Valve replacement was in 1960 performed with cusps of Teflon or Silicon rubber simulating the normal aortic cusps. From 1962 when it was found that all cusp-like valves ruptured after one to two years, the ball valve was adopted. In cases with narrow aortic roots, necessitating a No. 8 Starr-Edwards ball valve, such a high gradient, especially during exercise, was found that the method had to be abandoned.

The first tilting disc valve used at the Karolinska Sjukhuset was a Wada-Cutter valve in 11 cases. It was found that the two largest valves did malfunction already after two and eight months. Two embolized after three and five years but the two small valves looked intact and functioned excellent when they were exchanged to the Björk-Shiley tilting disc valves after five years. The lesson of this tilting disc valve was that the gradient was small whatsoever should be used and that a non-overlapping disc was less traumatic to the blood.

The Björk-Shiley tilting disc valve including this principle with a free floating rotating disc without any hinge and with a non-overlapping disc was introduced for clinical use in January, 1969. It had a Delrin disc that in 1971 was exchanged to an even more durable carbon pyrolytic disc, which in 1975 got a radiopaque marker for function control. Since 1976 I have only used a convexo-concave disc. The experience of 2000 case during 10 1/2 years' experience will be summarized:

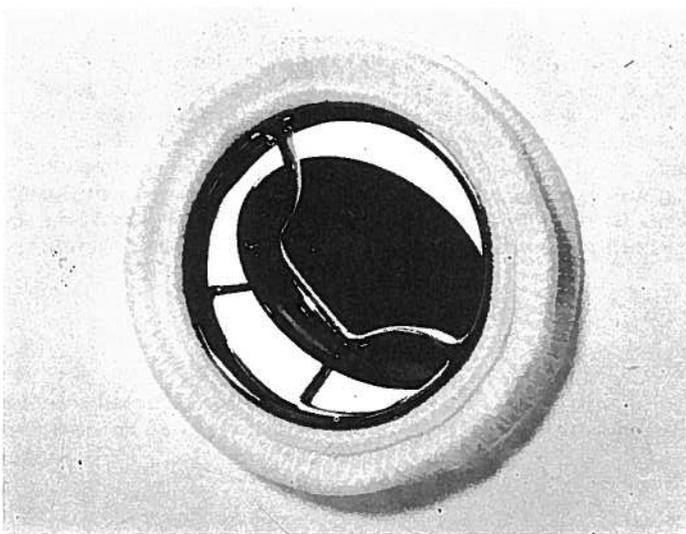


Fig. 1 — *The Björk-Shiley valve with the convexo-concave disc which in the open position creates a significant space between the disc and the ring.*

## THE VALVE CONSTRUCTION

For the first two years a Delrin disc was utilized. This functioned excellent and in the first ten cases, who after ten years have had a repeat aortography, we have not in any case found any increased insufficiency around the disc as compared to the first afterinvestigation performed one year after the operation. In 1971 the Delrin disc was exchanged to the even more durable carbon pyrolytic disc, which in 1975 got a radio-paque marker for function control with non-invasive fluoroscopy, which made it easy to see if the disc is fully open or closed. The non-overlapping disc is considered most important as it gives a 2 mm larger orifice for the same outside diameter. It also gives only half the red cell destruction in per cent per hour as compared to the overlapping disc. The standard disc is in direct contact with the ring in the fully open position, creating a stagnation and a low flow area behind the disc at this point, where a thrombus formation may start if anticoagulant therapy is not adequate. By making the disc convexo-concave, simulating an airplane wing which pivots 2 1/2 mm downstream and creating a space between the disc and the ring and enlarging the smaller hole by 40%, the space between the disc and the ring is becoming significant. (Fig. 1). When the disc in the open position this space will decrease the area of stagnation to only half when the flow velocity is measured by laser doppler 13 mm behind the valve orifice. In the convexo-concave version the velocity of flow through the small hole is also significantly increased compared to that in the standard version. Due to the shape of the convexo-concave disc only half the flow is necessary to keep the disc in the fully open position as compared to when a standard disc is used. The regurgitation has not increased with the convexo-concave disc and the gradient of the valve has decreased markedly. Thus, a 21 mm convexo-concave disc valve gives now the same gradient as the 23 mm standard model.

## DURABILITY

The durability was tested in a 21 mm aortic valve which was removed after six years and nine months in a patient. Only 0.5 microns, although pyrolytic carbon is 250 microns thick, was worn away. The critical surface tension of flange and disc had not been altered during this six years and nine months in the patient's circulation. The durability of the convexo-concave version has been tested in a pulse duplicator during a time comparable to nine years and it was found that 11 microns of 250 microns pyrolytic carbon was worn away. This is somewhat more than for the standard disc as a convexo-concave disc is closing 15% faster than the standard disc. At the same time the large strut has been made an integral part of the ring and is therefore three times stronger.

## MORTALITY

Operative plus 30 days mortality have been 5% for aortic valve replacement, 4% for mitral valve replacement, 10% for double valve replacement and 21% for triple valve replacement.

## COMPLICATIONS

Thrombotic obstruction with anticoagulation has been very low in aortic valve replacement and only 0.3/100 pat. ys. and 0 with aortic valve replacement with the convexo-concave disc. Mitral valve replacement has also shown a decrease from 1.3 to

0.9/100 pat. ys. of thrombotic obstruction utilizing the convexo-concave disc. Emboli has been 0.7/100 pat. ys. after aortic valve replacement and for mitral valve replacement emboli has come down from 3.2 to 1.2/100 pat. ys. utilizing the convexo-concave disc. Infection was encountered in 0.4/100 pat. ys. and paravalvular leakage in 2.4% for aortic valve replacement and 1.3% for mitral valve replacement.

The anticoagulation complication was 6.3 bleedings/100 pat. ys. with 0.2 fatal bleeding complication.

## RESULTS

At the follow-up the central circulation is significantly improved and the pulmonary artery mean pressure during exercise has decreased after aortic valve replacement from 45 to 29mmHg, after mitral valve replacement from 51 to 38mmHg, after double, aortic and mitral valve replacements from 59 to 39mmHg.

The ten years' actuarial survival for aortic valve replacement is 82% and the nine years' actuarial survival for mitral valve replacement is 70% when operative mortality is included.

In summary, after ten years' experience with 2000 Björk-Shiley tilting disc valves an excellent longterm function has been found. During this period it has been possible to further improve durability, flow dynamics, thrombo-resistance and function control into the present Björk-Shiley valve with the convexo-concave disc.

## RESUMO

### *PRÓTESE DE DISCO DE BJÖRK-SHILEY ANÁLISE DE UMA EXPERIÊNCIA SUPERIOR A 10 ANOS*

Neste artigo faz-se breve referência às válvulas utilizadas até à boa aceitação obtida pelas próteses de disco basculante. Descreve-se com mais pormenor a válvula de Björk-Shiley que passou por algumas transformações até que a mais recente, a de disco convexo côncavo, passou a ser utilizada em 1976.

Depois de fazer referência a alguns problemas da construção da prótese e da sua durabilidade, o autor menciona a experiência obtida em 2000 casos operados em 10 anos e meio finalizando com a descrição dos resultados obtidos.

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