Early Wear Development in a Novel Mechanical Heart Valve Prosthesis made from Polymeric Materials

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Background and aim of the study: **Currently, 95% of all implanted mechanical heart valve prostheses are constructed completely, or at least partially, from pyrolytic carbon. In order to develop a mechanical heart valve prosthesis made from alternative materials, a special hinge design was tested which enabled the integration of wear-resistant tribomaterials into the highly loaded hinges of leaflets.**

Methods: **The wear behavior of different material couples was investigated in vitro. Wear testing was performed using a specially designed durability tester that controlled the pressure difference across the closed heart valve prosthesis in a water-glycerol mixture with blood analog viscosity. Conditions were set according to FDA and ISO standards for heart valve testing. Qualitative assessment of wear behavior was performed using light microscopy and scanning electron microscopy at intervals of 10, 40, and each subsequent 50 million cycles.**

Results: **None of the investigated heart valve prostheses failed during the durability tests. Compared to the reference valve made from polymeric materials, wear especially in the hinges could be reduced to an acceptable level by integrating wear-resistant tribomaterials into the leaflets.**

Conclusion: **A leaflet design which enables the integration of tribomaterials into the highly loaded hinges of leaflets leads to an optimization of wear behavior of a mechanical heart valve prosthesis made from polymeric materials. Abrasive wear in the hinges may be reduced to an acceptable level for the functionality of the heart valve prosthesis. Durability tests will be continued in order to confirm the promising wear behavior of this novel heart valve prosthesis.**

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Subsequent to the pioneering cage-ball prosthesis developed by Hufnagel more than 50 years ago (1), a large variety of new valve designs has been developed to improve valve hemodynamics (2,3). These include caged-disc, tilting-disc, bileaflet, three-leaflet, bioprosthetic and flexible polyurethane polymer valves (4-7). The main problems associated with bioprosthetic and polyurethane polymer valves are an uncertain durability caused by leaflet calcification, and biodegradation of the biological tissue (8). Traditional problem areas of mechanical valves are mainly blood damage, thrombotic complications, and noise (9-11).

Since its introduction into the market in 1969, isotropic pyrolytic carbon has been the material of choice for mechanical heart valve prostheses (12), and today more than 95% of these valves are constructed completely, or at least partially, from pyrolytic carbon (13). The advantages of pyrolytic carbon are an inert behavior in biological tissues and a high wear resistance leading to a high long-term durability of mechanical valves, normally enduring a recipient's lifetime (14). The main disadvantage of pyrolytic carbon in mechanical heart valves is a prolonged manufacturing process and thus high costs (15).

The manufacturing costs are also an important aspect for new valve development. In order to reduce the costs of production for mechanical heart valves, alternative materials and manufacturing techniques must be considered. However, mechanical heart valves constructed from alternative materials require an optimized hinge or bearing configuration in order to guarantee a high functional safety and an appropriate lifetime comparable to that of pyrolytic carbon valves.

The present study details the early wear development in the hinges of a novel bileaflet mechanical heart valve. In order to improve wear behavior and to

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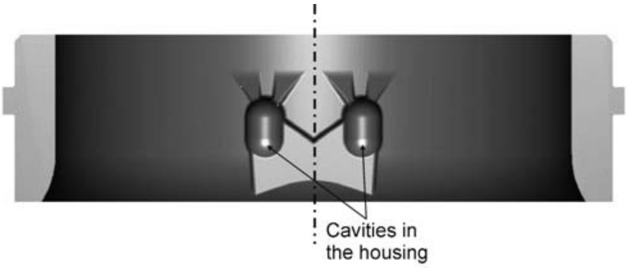

Figure 1: Cross-section of the valve housing of the HIA-Bileaflet valve.

increase durability of the heart valve, two different strategies were pursued. First, prototypes made from polymeric materials were coated with diamond-like carbon (DLC), layers of which are characterized by extreme hardness, a high wear resistance, and a low coefficient of friction (16). Second, wear-resistant tribomaterials were integrated into the highly loaded areas of the leaflet hinges. Initial prototypes of the heart valve prosthesis were manufactured in order to evaluate and compare the wear behavior of different material couples in vitro.

Materials and methods

The design and in-vitro performance of the novel Helmholtz Institute Aachen Bileaflet (HIA-BL) heart valve prosthesis has been described previously (17). Herein, only the hinge design of the valve is described in detail, since wear occurs mainly in the hinge region.

Hinge configuration

Hinge design is of major importance in mechanical heart valve prostheses. An optimized hinge or bearing configuration is required with respect to the high loads in order to guarantee a high functional safety and lifetime for a mechanical heart valve. Flow guidance in the bearing region is also important, as an inappropriate bearing design may lead to high turbulences, shear stresses and deadwater regions which could lead to additional blood damage or thrombotic complications (18,19).

The hinges between the housing and leaflets of the HIA-BL valve consist of cavities within the housing and mating leaflet extensions (Fig. 1). Each leaflet has a pair of spherical extensions which protrude from the leaflet and mate with the cavities of the housing. The leaflet is retained inside the housing and is moved passively by local pressure gradients. A self-cleaning effect of the hinges is achieved by the design of the housing cavities. The cavities are in the form of an elongated slot, and this facilitates an additional translatory movement of the leaflets prior to rotation. Thus, blood is pushed out of the cavities in the ring by each opening and closing movement of the leaflets.

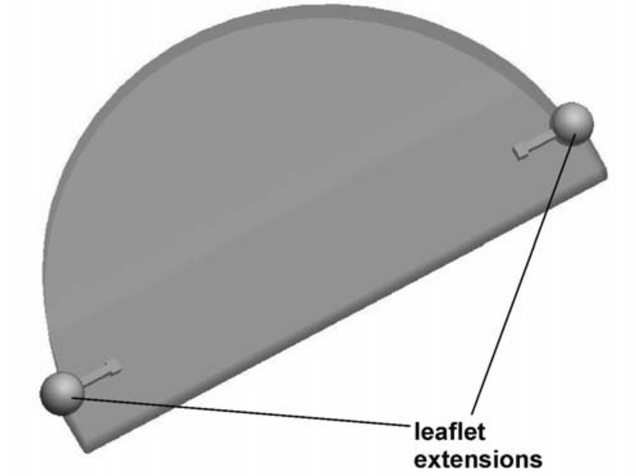

Figure 2: Shaded CAD model of the leaflet of the HIA-Bileaflet valve.

In order to increase the durability of the heart valve, it is possible to integrate wear-resistant materials into the leaflets. Balls with a protruding pin can be integrated into the hinges of the leaflets (Fig. 2). The connection between the inlays and leaflets is important for functionality of the heart valve prosthesis, with only a safe and reliable connection ensuring high functional safety of the valve.

Valves

Wear tests were performed with prototypes of the novel HIA-BL valve. The shape of the leaflets was modified in order to integrate inlays of different materials and to investigate the wear behavior of different material couples within a reasonable range (Fig. 3). Cylindrical pins with ball- shaped heads were stuck in mating holes in the leaflets. The influence of modifica-

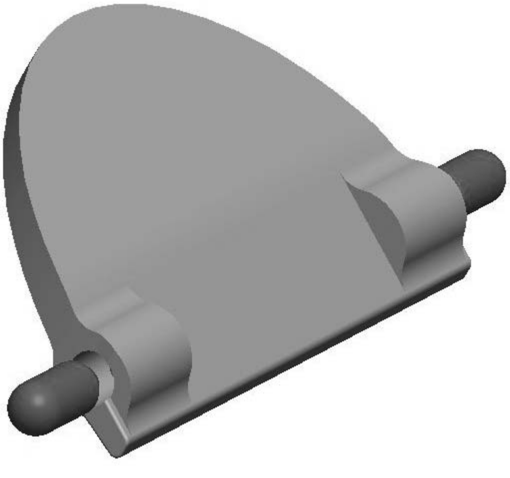

Figure 3: Shaded CAD model of the modified leaflet for the integration of inlays.

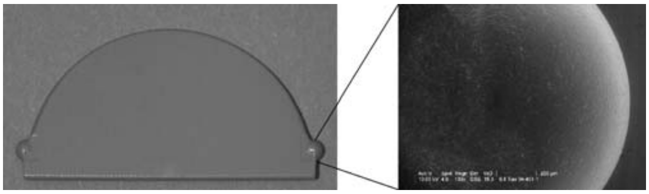

Figure 4: Investigated leaflet section using scanning electron microscopy.

tion on wear development was negligible, since it is axially symmetric to the rotation axis of the leaflets. Only the mass of the leaflets was slightly increased.

The materials used and material couples tested are listed in Table I. PEEK (polyetheretherketone), which was chosen as a polymeric material for the HIA-BL heart valve, is a high-performance polymer with sufficient biocompatibility and biostability. The leaflets are always constructed from this lightweight polymer in order to reduce the angular momentum of the moving parts of the heart valve.

The material chosen for the inlays is of major importance for durability of the heart valve. Ceramics are recognized for their almost inert behaviour in biological tissues, good biocompatibility, high wear resistance, and extreme hardness (>1000 Vickers). The titanium alloy Ti-6Al-4V was chosen as a metallic material for the inlays.

Housings were constructed from PEEK and Ti-6Al-4V, the latter being an appropriate material for cardiovascular implants since it is used as a housing material in several mechanical heart valve prostheses.

The surface microstructures of the harder material are responsible for the friction and wear behavior of a hard/soft material couple. A smooth and polished surface without protruding roughness peaks of the harder material leads to reduced wear rates of the tribological system.

Wear testing

The valves were tested in the Helmholtz Institute Aachen Fatigue Tester II (HIA-FT II), the design and details of which have been described elsewhere (20). All valves were tested according to FDA and ISO standards, and were fixed in separate test compartments without a sewing ring. An optical inspection of the valves was carried out daily. The mean (±SD) pressure difference across the closed valves was 120 ± 25 mmHg. Tests were performed in a water-glycerol mixture with blood analog viscosity (3.6 mPa·s) and a testing rate of 600 beats per min. At each inspection interval the valves were cleaned in an ultrasonic bath and dried in a stream of cleaned compressed air.

Table I: Material couples employed in heart valve testing.

Couple	Housing	Leaflet
1	PEEK	PEEK
2	PEEK DLC-coated	PEEK DLC-coated
3	PEEK	Ti-6Al-4V
4	PEEK	Al_2O_3
5	PEEK	ZrO_2
6	Ti-6Al-4V	Al_2O_3
7	Ti-6Al-4V	ZrO_2

The pivots of housings and the leaflets were inspected qualitatively. Pivot cavities inside the housing were inspected using light microscopy (LM) at each interval. Leaflets were inspected by using LM and scanning electron microscopy (SEM) which was performed at the University Hospital Aachen. Figure 4 illustrates the section of leaflets investigated by SEM.

Profilometry was not used for this wear study, as a reproducible positioning of the valve components at each testing interval was not successful.

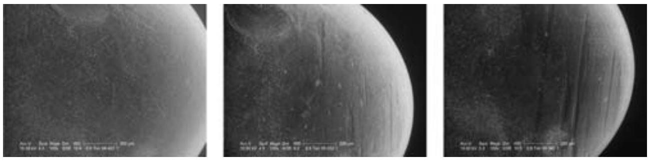

Figure 5: Scanning electron microscopy images of the reference valve of PEEK. Left: before testing. Center: after 80 million load cycles. Right: after 200 million load cycles.

Results

A reference valve with leaflets and housing constructed from PEEK was tested for 200 million load cycles in the HIA-FT II durability tester. Figure 5 shows SEM images of the reference valve before and after testing. Traces of abrasive wear can be clearly seen on the highly loaded leaflet extensions, and deep wear furrows have formed as a consequence of the tribological stresses. With ongoing durability tests the wear furrows on the PEEK leaflets increased in size.

DLC-coated leaflets were run in DLC-coated housings for 200 million load cycles. SEM images of a DLC-coated valve before and after testing are shown in Figure 6. Compared to the reference valve, the DLC

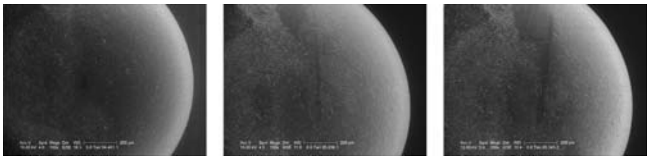

Figure 6: Scanning electron microscopy images of the DLC-coated valve. Left: before testing. Center: after 80 million load cycles. Right: after 200 million load cycles.

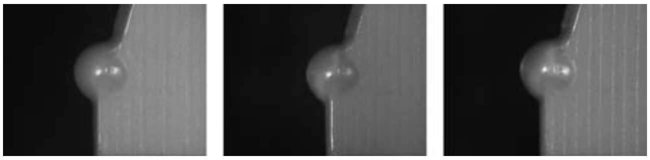

Figure 7: Light microscopy images of the DLC-coated valve. Left: before testing. Center: after 80 million load cycles. Right: after 200 million load cycles.

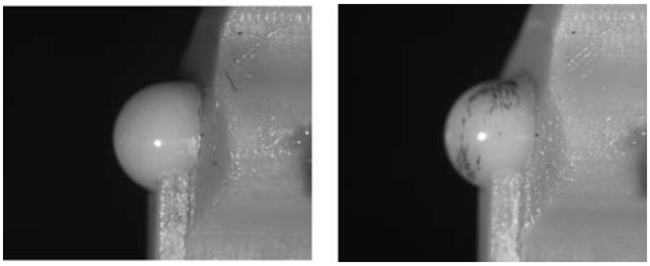

Figure 8: Light microscopy images of a ZrO_2 inlay run in a Ti-6Al-4V housing. Left: before testing. Right: after 10 million load cycles.

Figure 9: Scanning electron microscopy images of a Ti-6Al-4V inlay run in a PEEK housing. Left: before testing. Center: after 40 million load cycles. Right: after 140 million load cycles.

Figure 10: Scanning electron microscopy images of a ZrO_2 inlay run in a PEEK housing. Left: before testing. Center: after 40 million load cycles. Right: after 90 million load cycles.

coating clearly reduced abrasive wear in the leaflet extensions and enhanced wear resistance of the heart valve. One problem encountered was the low bond strength between the DLC coating and the PEEK substrate. After 10 million load cycles the DLC coating was partially worn out such that the substrate material could be seen at the leaflet hinges (Fig. 7). The visible area of substrate grew with ongoing durability tests.

A ceramic/metal material couple is considered to be an incorrect combination for use in a mechanical heart valve prosthesis. Al_2O_3 respectively ZrO_2 inlays were integrated into the leaflets and run in a housing made from Ti-6Al-4V. A LM image of a ceramic inlay before testing and after the first inspection interval (10 million load cycles) is shown in Figure 8. As a consequence of the porosity of the ceramics and adhesive wear, a metallic layer was visible on the ceramic inlays. This wear behavior was observed for both tested ceramic/metal material couples.

A ceramic/polymer and a metal/polymer material couple represents a reasonable combination for a mechanical heart valve prosthesis. During the durability tests no signs of adhesive wear were found on either the ceramic inlays or in the housing.

The integration of inlays made from Ti-6Al-4V in the leaflets reduced abrasive wear in the leaflet hinges compared to the material couple PEEK/PEEK. However, as a result of the low wear resistance of Ti-6Al-4V, traces of wear were visible in the SEM images after 140 million load cycles (Fig. 9).

The material couple ZrO_2/PEEK showed no signs of wear after 90 million load cycles. SEM images of the ZrO_2 inlays integrated into the leaflets before durability testing and after 90 million load cycles are shown in Figure 10. The surface of the ZrO_2 inlays appeared smooth and polished, and showed no signs of abrasive wear.

The material couple Al_2O_3/PEEK should also have the potential to increase the durability of a heart valve prosthesis. However, the SEM image shown in Figure 11 of an alumina inlay before durability testing revealed several surface defects which could be attributed to the manufacturing process. The rough surface of the hard alumina inlays led to increased wear in the

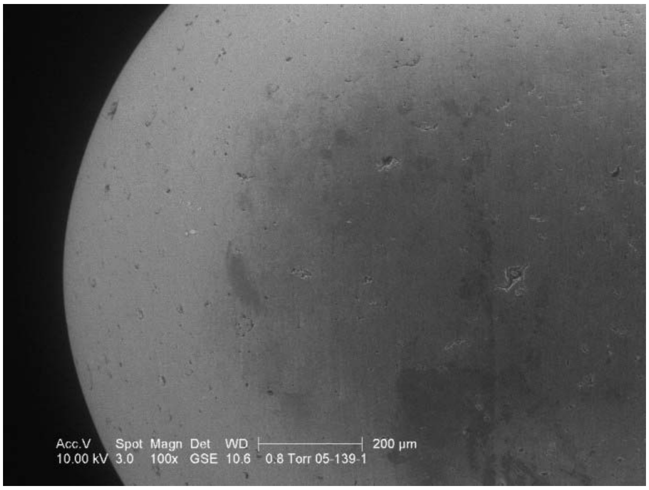

Figure 11: Scanning electron microscopy image of a Al_2O_3 inlay before the durability tests.

pivot cavities in the housing, which was constructed from a soft polymer.

The cavities in the housing did not show any signs of increased wear after testing. Indeed, the wear caused neither leaflet escape nor visible cracks or pittings in the housing cavities.

Functionality of the valves was investigated after testing in a pulse duplicator under physiological flow conditions. All valves performed well, and functionality was not affected by wear in the HIA-BL heart valve.

Discussion

As expected, a mechanical heart valve constructed entirely from PEEK showed the largest wear traces in the highly loaded leaflet hinge areas of all tested material couples. After 200 million load cycles, several wear grooves were visible on the SEM images of the leaflet extensions, although functionality of the heart valve prosthesis was not impaired by the wear.

Two different strategies may be pursued in order to improve the long-term durability of a mechanical heart valve prosthesis made from polymeric materials. Coating of the valve components with a DLC layer clearly reduced abrasive wear in the leaflet extensions and provided a distinct improvement in wear resistance of the prosthesis. One problem was the early exposure of the substrate material after only a few million load cycles. The DLC layer was partially damaged in the high-loaded hinges as a consequence of both impact and friction forces. The exposed area of the PEEK substrate grew over increasing load cycles. As a consequence, the DLC layer would be removed completely after a certain number of load cycles, at which time an increased abrasive wear could be expected.

A further possible means of improving the wear resistance of the heart valve prosthesis is the integration of inlays made from suitable wear-resistant materials in the highly loaded hinge areas of the leaflets. The integration of metallic and ceramic materials diminished abrasive wear in the leaflet extensions and led to an increased durability of the heart valve prosthesis. The best results were obtained by integrating ZrO_2 inlays, this being due to the outstanding wear properties of this ceramic material. Following testing, there were no traces of wear visible in the SEM images of the leaflet extensions.

The early wear development of the HIA-BL heart valve is promising. In particular, the integration of inlays into the leaflets seemed a suitable possible means of increasing wear resistance of the heart valve to a sufficient level. Suitable material couples for further long-term studies have been identified, and durability tests are ongoing at the Helmholtz Institute in order to further analyze the long-term durability of the HIA-BL heart valve prosthesis. This approach may lead to the development of a cost-effective mechanical heart valve prosthesis with sufficient long-term durability and high functional reliability.

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