Characterization of Explanted Bileaflet Mechanical Heart Valves and Correlation with Patients' Clinical Data

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Abstract
The analysis of explanted mechanical heart valves (MHVs) is an essential source of information about the effects of their *in vivo* working. In order to better understand the mechanisms arising from the interaction between MHVs and biological environment, in this study fourteen bileaflet valves were considered. From clinical data, all the malfunctioning valves showed a high degree of stenosis. By investigations on the MHVs components and the study of the clinical data, it was possible to establish that the ordinary abrasive wear does not involve clinical disease. On the contrary, impact wear and/or surface defects, due to improper surface finishing, can generate rough areas and consequently thrombogenic sites. The growth of fibrotic tissue can modify the cinematic coupling with serious alteration of the leaflet motion. This work demonstrates the feasibility of creating a database to statistically analyze the results with the aim of improving valves design and surgical operation.

1. Introduction
Surgical correction of valvular heart disease has become a common medical procedure, with several thousand of operations executed every year. Three models of Mechanical Heart Valves (MHVs) are commercially available: i.e., caged ball, tilting disk and bileaflet. The first successful mechanical heart valve was proposed at the beginning of 1960's and was the caged-ball model. It has been used even after tilting disc valves were commercially available. Nowadays, many surgeons still consider caged-ball valves very reliable. Tilting disc MHVs were used mainly from 1975 to 1895 [1]. Bileaflet valves were introduced in the early 80's (the first St.Jude bileaflet was implanted in 1977), but had been extensively used from 1996. Nowadays, most implanted mechanical valves are bileaflet ones. The great success of this valve model is due to its design permitting improved blood flow and, possibly, also to some fashion effect. In fact, clinical outcome does not provide evidence for any beneficial effect over other valve models [2].
Materials usually employed for mechanical heart valve manufacture include: CoCr alloys, Ti and its alloys for the housing, and PTFE or PET for the suture ring often coated with pyrolitic carbon to increase their hemocompatibility [3]. Silicon rubber, polyoxymethylene (Delrin®), graphite coated with pyrolitic carbon are often used for the occluder. In the first fifty years of MHVs use, valve design and materials used have been dramatically improved, resulting in striking

success but also in failures sometimes with dramatic consequences on patient health [4]. The failure mechanism of mechanical valves can be classified into two main categories: the intrinsic and the extrinsic mechanism. Failure by intrinsic mechanisms is related to heart valve design or material properties, i.e. fatigue fracture, abrasive wear or polymer degradation. Possible consequences of failure of the intrinsic mechanism could be: (1) alteration of the kinematics coupling between occluder and housing; (2) break of the occluder; (3) exposure of thrombogenic surfaces; (4) material release. The extrinsic mechanism consists in externally generated interference with the motion of the valve occluder (i.e., causing thrombosis, thromboembolism, endocarditis, or bleeding). Different and unpredictable conditions can arise as a consequence of mechanical heart valve implantation, due to the body interacting with foreign materials and subsequent effects. As a result, the working conditions under which the valves function may differ greatly from those expected. Although *in vitro* wear tests can help to provide an understanding of wear mechanisms and may predict the type of surface that will be more effective, it is impossible to reproduce totally and correctly the conditions that will be encountered *in vivo* [5,6]. Consequently, it is very important to determine which type of interaction has occurred during *in vivo* operation of the valve, and the role played by the damage to the materials from which the valve is constructed [7].

In the present study, twenty-five explanted bileaflet mechanical heart valves, completely of only partly coated with pyrolitic carbon, were analyzed to understand the effects of material problems on valve performance and patients' general health conditions. Wear patterns and defects observed on the MHV components were analyzed to study the general state of the prosthesis, to search for evidence of intrinsic failure mechanism (if present), and, finally, to correlate this information with clinical data (e.g., cause of re-operation, transvalvular gradient, etc.).

2. Materials and Methods

2.1 Bileaflet explanted valves

Twenty-five explanted bileaflet MHVs (8 St. Jude, 12 Sorin Bicarbon, 4 Sorin CarbonArt, and 1 Edwards-Durometrics) were analyzed (Table 1). The reference number of each of the explanted valves, together with related clinical data, are provided in Table 1.

2.2 Analysis of explanted valves

After explantation, the valves were stored in Phosphate Buffered Solution (PBS Sigma, 0.01M in distilled water) at 4 °C. An enzymatic digestion of the residual biological tissues was performed using pancreatin. At the end of the cleaning procedure, the valves were dried at 37 °C for 48 h and maintained at r.t. until characterization.

2.3 Surface analysis

Following an initial examination using a stereo microscope (Leica/Wild Heerbrugg M8), the valves were gold-sputtered (Edwards S150B, operating at 0.2 mbar, 1 kV, 20 mA for 1 min) and then analyzed using scanning electron microscopy (StereoScan 360; Cambridge Instruments) and energy-dispersive X-ray spectroscopy (Oxford INCA Energy 200).

For each valve, the occluder was separated from the housing by slightly deforming the housing, and examined by optical microscopy (Leica DMLM system), while the sewing rings were examined with stereo optical microscopy.

Table 1 – Clinical data for the explanted bileaflet heart valves

Valve number	Patient gender	Age @ explant (years)	Valve Model	Valve position	Implant duration (months)	TVG (mmHg)		Valve function	Reason for explant
						average	max		
2	F	51	St Jude	aortic	144	89	136	normal	aortic aneurism
11	F	12	St Jude	mitral	120	17	26	abnormal	malfunction
15	M	65	St Jude	aortic	168	48	72	abnormal	malfunction
16	M	67	St Jude	aortic	88	*	*	normal	detached
22	F	58	St Jude	aortic	156	56	90	abnormal	malfunction
23	F	65	St Jude	aortic	76	55	95	abnormal	malfunction
25	M	27	St Jude	aortic	154	20	35	normal	aortic aneurism
49	F	55	St Jude	aortic	180	53	109	abnormal	malfunction
7	M	22	Sorin Bicarbon	aortic	90	17	29	normal	aortic aneurism
14	M	22	Sorin Bicarbon	mitral	11	*	*	normal	card transpl
26	M	59	Sorin Bicarbon	aortic	106	10	19	normal	card transpl
27	M	37	Sorin Bicarbon	aortic	18	*	*	normal	aortic aneurism
28	M	53	Sorin Bicarbon	mitral	15	5	19	normal	detached
30	F	63	Sorin Bicarbon	mitral	36	7	18	normal	detached
34	M	51	Sorin Bicarbon	aortic	105	61	97	abnormal	thrombosis
38	M	42	Sorin Bicarbon	aortic	3	*	*	normal	endocarditis
39	F	54	Sorin Bicarbon	mitral	16	10	30	abnormal	thrombosis
46	M	69	Sorin Bicarbon	mitral	58	8	20	abnormal	thrombosis
56	M	67	Sorin Bicarbon	aortic	2	26	55	normal	endocarditis
57	M	66	Sorin Bicarbon	mitral	3	*	*	*	endocarditis
35	M	62	Sorin CarbonArt	aortic	37	8	17	normal	endocarditis
40	M	30	Sorin CarbonArt	aortic	4	*	*	normal	endocarditis
47	M	40	Sorin CarbonArt	aortic	9	*	*	normal	endocarditis
52	M	52	Sorin CarbonArt	aortic	60	*	*	normal	endocarditis
8	F	65	Edwards-Duromedics	aortic	180	44	80	abnormal	malfunction

M: male; F: female; TVG: tranvalvular gradient; *: data not available; card transpl: cardiac transplantation

2.4 Dimensional analysis

Before valve disassembling the housing diameter was measured with a caliper (TESA, artichoke 05) to exclude possible changes of geometry, or deformations due to the *in vivo* working. The diameter was measured in four positions referred to a selected point (Fig.1), and the average value was calculated.

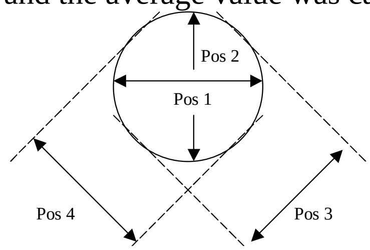


Figure 1 – Position of housing size analysis

2.5 Dynamic Mechanical Analysis

Tensile tests were conducted using a dynamic-mechanical analyzer (TA Instruments, DMA 2980). Tests were designed and performed on specimens (n=3) cut from the sewing rings in order to evaluate any possible degradation of the polymeric material. DMA tensile tests were carried out with a stress ramp in tensile mode, at a rate of 0.1 N/min at 37 °C, using Ethilon 5/0 as the suture yarn and polyurethane as the counterpart of the sewing ring specimen (Fig.2).

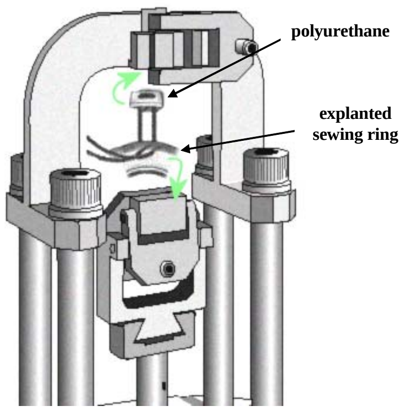


Figure 2 - Scheme of the DMA apparatus for test on suture rings

3. Results and Discussion

3.1 Clinical data

Among the considered MHVs, 9 valves were implanted in women, and 19 in men; 20 valves were implanted in aortic position and 8 valves in the mitral position (Table 1). The patients age at valve implant ranged from 12 years (#11) to 69 years (#46). As possible to observe in figures 3a and 3b, no correlation was identified among the age and the gender of the patients, nor the duration of implantation.

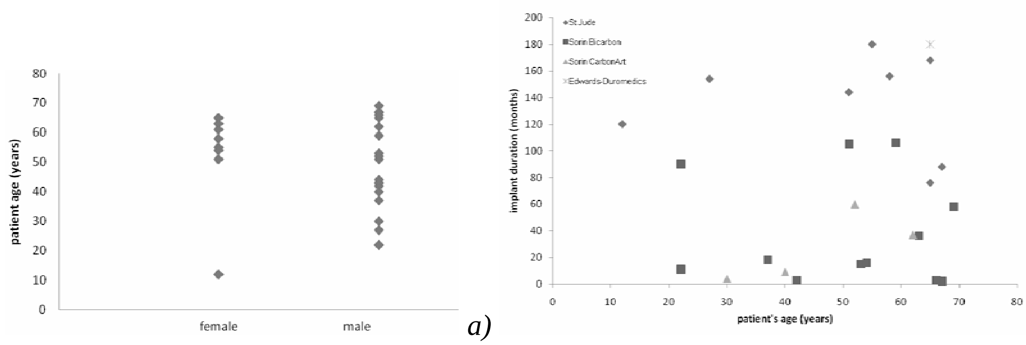


Figure 3 – a) Patient’s gender *vs* patient’s age; b) patient’s age *vs* implant duration. No correlation can be evidenced.

From clinical data, different reasons for explantation were evidenced (Figure 4); in particular, all the malfunctioning valves showed a high degree of stenosis, confirmed by the high values of the transvalvular gradients, as observed, for example, for valves #22, and #23. After explantation, for 11 valves the presence of pannus or thrombus formation was observed (Figure 5). Furthermore, for different prosthesis, the high values of the transvalvular gradients can be attributed to the difficult movement of the two leaflets. For valves #2 (size 21), #15 (size 21), and #25 (size 23), the values of pressure gradients are higher than those expected for the St Jude valve model (i.e. 14.4±8.3 mmHg, 7.2±2.2 mmHg, respectively for max and average gradient [8]). For two valves (valves #7 and #27) the malfunction was hidden by more severe pathology (i.e. aneurism of the ascendant aorta).

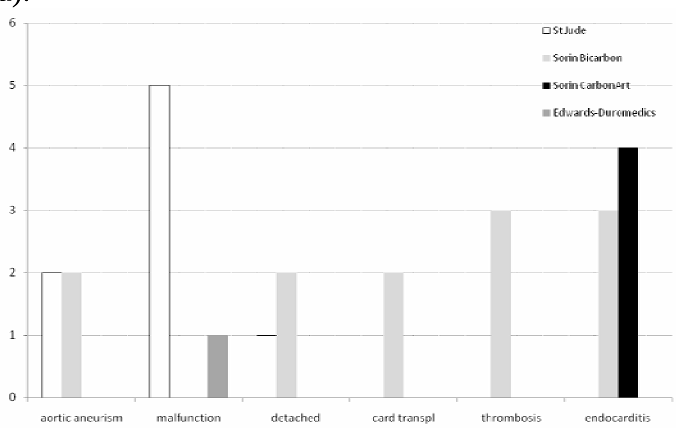


Figure 4 – Different reason for explanation for each model of investigated bileaflet valves

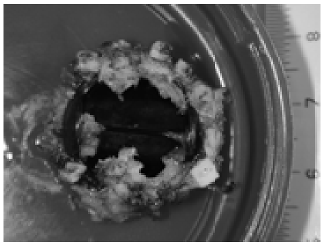
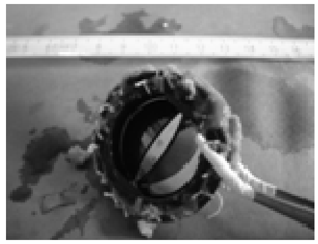
 a)  b)  c)

Figure 5 – Pannus on the suture ring, the correct motion of the two leaflets is obstructed: a) St Jude valve #23; b) Sorin Bicarbon #57; c) Carbomedics #36

3.2 Macroscopic and microscopic analysis

St Jude MHVs

The St. Jude Mechanical Heart Valve was the first heart valve prosthesis that used two component coated by pyrolitic carbon (PyC) for the cinematic coupling with concentrate wear, as the one between hinges and pivots. The first studies performed in vitro demonstrated that wear of the PyC coated pivots did not cause malfunction or break [4]. In fact, the abrasive wear detected in all the 8 analyzed valves was not directly correlated to a clinical symptomatology. The effects of the abrasive wear are more evident in the zones of relative motion between the housing and the two leaflets (Figure 6a,b and figure 6c). In the St Jude prosthesis, the transvalvular pressure during the closure cause a maximum load on the leaflets and is sustained by the tips of the two leaflets [4]. High load and impact among the leaflets and the hinges can explain the presence of scratches on the pivots of the MHVs #2 and #25. Furthermore, high loads could give rise to the isles with a marked porosity, observed in the hinge of valves #15, #22 (Figure 7a). On the contrary the bright areas, characterized by a high porosity (figure 7b), observed on the leaflets and on the rim and the outer surface of the housing of valves #23 and #25 are most likely due to an imperfect surface finishing process rather than to mechanical damage, for their position out of the areas of high load and impact. The scratches on the pivots could have changed the cinematic coupling between the two leaflets and the housing, preventing the normal movement of the occluders, and promote the pannus growth (i.e. rough surface). Also the zone of the hinges with high porosity could have caused the growth of fibrotic tissue.

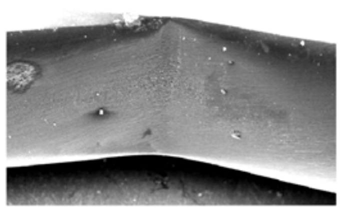
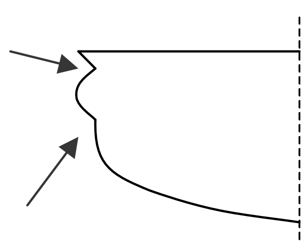
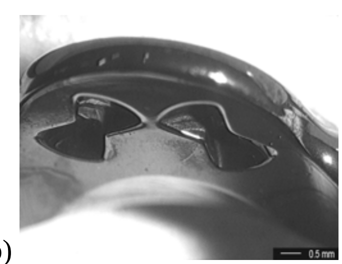
 a)  b)  c)

Figure 6 – a) Scratches on the leaflet near the pivots and b) their position; c) scratches inside the hinges

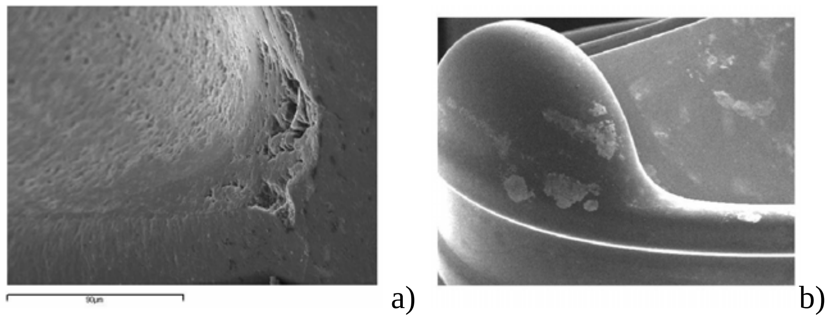


Figure 7 – Housing of valve #15 porous surface in the hinge (a); valve #23 porous areas on the outer surface of the housing and in the centre of the leaflets (b)

Sorin MHVs

The Sorin valve prosthesis was designed to promote a low thrombogenicity caused by the improvement in fluid dynamics and an innovative mechanism for the cinematic coupling between the housing and the two leaflets. The design of leaflets and hinges allows to have only a rolling movement, decreasing wear and friction. *In vitro* fatigue tests demonstrated the absence of structural failure after 400 million of cycles (corresponding to 11 years *in vivo* functioning) and allowed to observe the distribution of worn surface in the hinges [9]. A study by Hasenkam et al. [10] demonstrated that the more evident wear marks are present on the surface of the pivots in the inlet side. The effects of wear on the housing were also analyzed, evidencing the presence of delamination of the PyC coating most of all in the inner zone of the hinges [10]. All the Sorin prosthesis considered in this work exhibited scratches due to abrasive and impact wear phenomena, in accordance with the in vitro and in vivo studies [9,10]. In particular, on valve #7, implanted for 8 years, wear scratches were observed (Figure 8, and Figure 9), accordingly with the ones found by Hasenkam et al. [10]. The other Sorin valves, implanted for 11-18 months, showed wear pattern less evident as demonstrated also by Grigioni et al. [9]. For valve #27 (implanted for 18 months) evident scratches due to wear phenomenon were detected, probably due to defects in the surface finishing process (Figure 10).

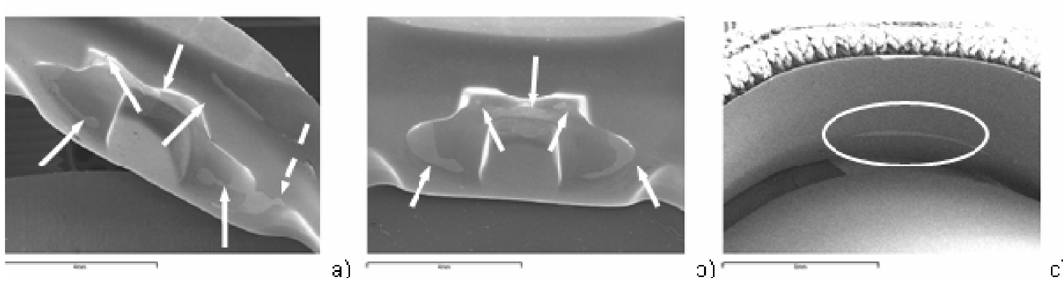


Figure 8 – Detachments of the PyC coating in the two hinges (in and out, a, b respectively) and in the housing (c).

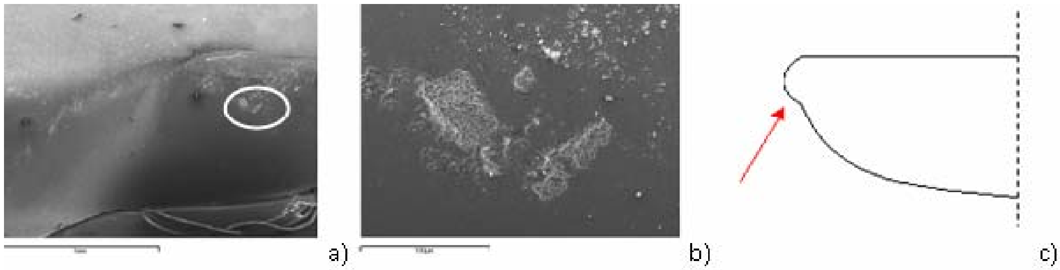


Figure 9 – Porosity of the pivots surface (a), same surface at higher magnification, the porosity is more evident (b), position on the leaflet (c).

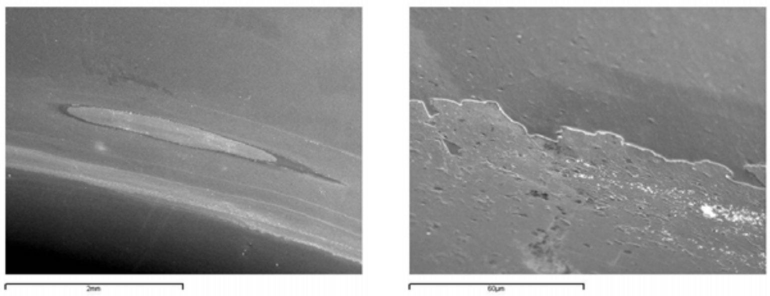


Figure 10 – Scratches and PyC coating detachment correlated to defects in the surface finishing process

Edwards-Duromedics MHV

The Edwards-Duromedics valve has been designed, differently from St Jude and Sorin models, to distribute load on a large surface of the leaflet during the closure phase. Tests in vitro performed for 400 million of cycles demonstrated that wear is homogeneously distributed on a larger area than for the other valve models (ex. St Jude or Sorin) [4].

The analyzed valve, implanted for 15 years, showed a slight wear; the pivots, for example, did not exhibit any scratch. The only impact wear evidence is located in the groove that lock the leaflet during its closure (Figure 11). This cycle step is the one more critical for the material resistance; in fact the most worn zones in the inner part of the hinges are the ones in which the pivots hit when the valve is closed.

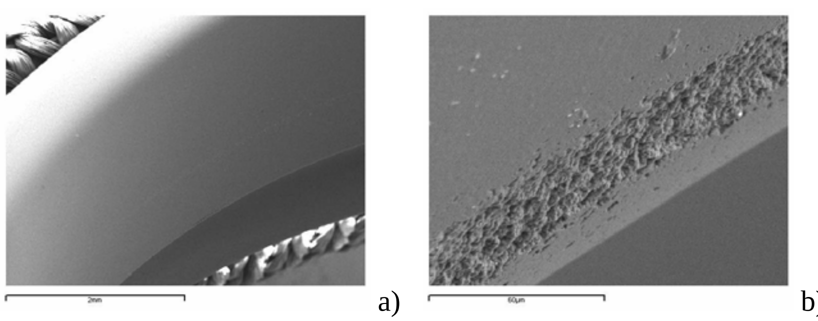


Figure 11 – Scratch due to impact wear in the housing (a), and porous surface of the scratch

3.3 Dimensional analysis

No changes were detected in the housing diameters for all the model of bileaflet valves under investigation.

3.4 Sewing rings

No change in tensile mechanical properties were observed for any of the valves; that is, there was no polymer degradation. Under the tensile test conditions used, no breaks were detected in any of the sewing rings.

4. Conclusions

Bileaflet valves represent the last level of the evolution in the design of the mechanical heart valve, causing many improvements in the hemo- and bio-compatibility with the human body. Wear effects have been observed in the sites where high load concentration was expected by design consideration but no direct consequence on clinical symptomatology was assessed.

Even if many problems have been resolved, other ones are yet open, as thrombo-embolism phenomena and pannus formation, as also reported in this analysis.

In fact, the analysis performed in this study have demonstrated the formation of pannus on almost all the 24 considered valves, sometimes compromising the movement of the two leaflets. Furthermore, the presence of pannus short time after the implantation is in accordance with literature data [11].

Among ST Jude and Sorin Bicarbon bileaflet valves no considerable difference were observed.

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