Pilot Licensing after Aortic Valve Surgery

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Background and aim of the study: **Bicuspid aortic valve is the most common congenital heart malformation, and a high percentage of patients with this condition will develop complications over time. It is rare that pilots undergo aortic valve surgery, and the confirmation of flight-licensing requirements after aortic valve replacement (AVR) is a challenge for the patient's cardiac surgeon and, particularly, for the Aeromedical Examiner (AME). Only AMEs are able to determine the flight status of pilots. Furthermore, in military and in civil aviation (e.g., Red Bull Air Race), the high G-load environment experienced by pilots is an exceptional physiological parameter, which must be considered postoperatively.**
Methods: **A review was conducted of the aeronautical, surgical and medical literature, and of European pilot-licensing regulations. Case studies are also reported for two Swiss Air Force pilots.**
Results: **According to European legislation, pilots can return to flight duty from the sixth postoperative month, with the following limitations: that an aortic bioprosthesis presents no restrictions in cardiac function, requires no cardioactive medications, yet requires a flight operation with co-pilot, the avoidance of accelerations over +3 Gz and, in military aviation, restricts the pilot to non-ejection-seat aircraft. The patient follow up must include both echocardiographic and rhythm assessments every six months. Mechanical prostheses cannot be certified because the required anticoagulation therapy is a disqualifying condition for pilot licensing.**
Conclusion: **Pilot licensing after aortic valve surgery is possible, but with restrictions. The +Gz exposition is of concern in both military and civilian aviation (aerobatics). The choice of bioprosthesis type and size is determinant. Pericardial and stentless valves seem to show better flow characteristics under high-output conditions. Repetitive cardiological controls are mandatory for the early assessment of structural valve disease and rhythm disturbances. A pre-emptive timing is recommended when reoperation is indicated, without waiting for clinical manifestations of structural valve disease.**

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The bicuspid aortic valve (BAV) is the most common congenital heart malformation, affecting up to 2% of the population (1), while the remainder of heart malformations total only 0.8%. More than 33% of the affected patients with bicuspid valves will eventually develop complications. Dilatation of the aorta must be closely controlled in the presence of BAV (2): aortic root replacement surgery is indicated earlier (diameter of 45-50 mm) than in those patients with tricuspid aortic valves (diameter >55 mm) (3-7). Alternative techniques, such as tricuspidization to restore a normal valve function, have been described by Prêtre et al. (8) and Anderson (9). Whilst this technique may offer promise under certain circumstances, long-term results are still lacking. Cardiac surgery is rare in pilots, and even rarer in military pilots. The flight-licensing procedure for the return to duty of a pilot represents a challenge for both the cardiac surgeon and the Aeromedical Examiner (AME), the latter being the only physician competent to determine the flight status of a pilot. To date, only one case of aortic valve replacement (AVR) in a United States Air Force pilot has been reported (10).

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Particularity of aortic valve surgery in pilots

International medical requirements for pilot licensing apply many limitations to therapeutic options. Anticoagulation is a disqualifying condition for pilot licensing. Safety issues focus particularly on sudden incapacitation, such as arrhythmias or embolic disorders. The surgeon must pay particular attention to the choice of prosthetic material. The statistical evidence for hazard limitation is an established rule in aviation. In both military and civilian aviation (aerobatics, e.g., Red Bull Air Race), the high G-load causing sustained Valsalva maneuvers and high cardiac output phases, is a very particular parameter to be considered. Hence, communication and coordination between the cardiac surgeon and the AME in charge of the diseased pilot are of central importance.

The concept of risk assessment from the European JAA and ICAO

The concept of aeromedical fitness is established in Europe in the 2009 Joint Aviation Authorities (JAA) Manual of Civil Aviation Medicine (Chapter 1, General, Amendment 6, The Concept of Aeromedical Fitness, pages 1-2) (11), and in the 2008 International Civil Aviation Organization (ICAO) Manual of Civil Aviation Medicine (Part I, Chapter 2, Medical Requirements) (12). The postoperative assessment of the pilots is determined by the '1% rule' for the flight crew incapacitation. A value of 1% per year corresponds to one incapacitating event per 100 pilot-years. For a professional pilot, a yearly 1% risk of sudden incapacitation fulfills the safety limitations. This rate is equivalent to the best outcome after cardiac surgery. Cardiovascular diseases accounts for 50% of the invalidation of pilot licenses in Western Europe, and represent the most common causes of sudden incapacitation (JAA Manual of Civil Aviation Medicine, Chapter 2, Cardiology, Amendment 5, Paragraph 8.4, Valvular Surgery, page 14 (11), and ICAO Manual of Civil Aviation Medicine, Part III, Chapter 1, Cardiovascular System, pages 32-33 (13)).

The 1% safety rule

The average duration of a flight is 1 h, and the health of the pilots totals about 10% of the operational risks. The current accident rate with fatal consequences in air transportation is about 0.1 per million flying hours. In a two-man-operation aircraft, the risk of a double sudden incapacitation for the aircraft is rarer than 1 per 10^{12} flying hours. In the worst-case scenario, a pilot with a yearly 1% risk of sudden incapacitation will jeopardize one of one million flights. While only 10% of the flight is considered critical (take off and landing), this corresponds to one endangerment of an aircraft in 10 million flights. Assuming that only 1% of the handovers in double cockpit fail, only one fatal event will be due to medical causes in one billion flights.

Therefore, medical reasons for a fatal accident are not responsible for more than one case per billion flying hours (JAA Manual of Civil Aviation Medicine, Chapter 1, General, Amendment 6, The Concept of Aeromedical Risk Assessment, pages 5-6 (11), and ICAO Manual of Civil Aviation Medicine, Part I, Chapter 3, Licensing Practices, pages 2-3 (12)).

Case reports

A 34-year-old pilot underwent surgery due to the development of a high gradient across a BAV. The patient was asymptomatic and well compensated, and the diameter of the ascending aorta was 37 mm at the time of surgery. A second pilot was aged 50 years at the time of surgery. After having been in stable clinical condition over the years, and without any cardiovascular complications, this patient developed a rapidly progressive and decompensating high-grade aortic regurgitation (BAV), with new-onset arrhythmias and severe dyspnea. The diameter of the ascending aorta was 56 mm at the time of surgery.

In both cases, a Carpentier-Edwards Perimount 27 mm stented pericardial bioprosthesis was implanted. In the latter setting of the dilated ascending aorta, a reduction aortoplasty and mesh wrapping were performed. Follow up echocardiographic controls were scheduled at every 12 months. Individual pilot-licensing limitations were defined nine months after surgery, based on the JAR-FCL 3 (Section 1, Subpart B - Class 1 Medical Requirements, Paragraph 3.150, page 1-B-2) (14), on the clinical findings, and on advice from the flight cardiologist and cardiac surgeons. The 34-year-old pilot had shown transient turbulent transvalvular flow through the prosthetic valve at the first echocardiographic examination three months after surgery. His license limitations were: medical class 1, valid only as or with qualified co-pilot (operational multicrew operation; OML), medical class 2 with safety pilot (operational safety pilot limitation; OSL), Pilatus PC-7 (low-wing tandem-seat, single-engine turboprop training aircraft manufactured by Pilatus Aircraft of Switzerland) solo and jet-passenger (PAX) without G-straining maneuvers over +3 Gz (gravity multiples in vertical axis to aircraft). The 50-year-old pilot had regular postoperative control examinations. His license limitations were: medical class 1 OML, Pilatus PC-7 solo with G-load not over +3 Gz.

Criteria for the choice of aortic valve prosthesis in pilots (15,16)

Determinative for the evaluation of the performance of an aortic implant is the transvalvular fluid dynamic performance profile, as determined by the effective orifice area (EOA), the valve-related flow profile, the transvalvular gradient, and the aging profile of the implanted material (17). The slope of the gradient increase under high-output conditions should also be as flat as possible. The flow characteristics under high-output conditions depend on the size of the prosthesis (EOA; Bernoulli's law), the material (porcine versus pericardial), and whether the valve is stented or not (annular compliance) (17-25). Although tissue prostheses are widely available, double-leaflet carbon valves have good hemodynamic performances but require lifelong anticoagulation, which is a disqualifying condition for flight licensing (11,13,14). The use of a homograft may be considered, but the scarce availability of homografts limits their use most commonly to life-threatening endocarditis. Alternatively, the Ross procedure may be used, but this involves a more demanding surgery that affects two valves, and is limited to centers with the most experienced surgeons. Pilots are highly active patients, and require valves with a priority on a low transvalvular gradient under high-output conditions.

Valve-related complications and flight safety

Four relevant complications must be considered (26,27), namely structural valve deterioration (SVD), non-structural dysfunction (NSD), thromboembolism (TE), and prosthetic valve endocarditis (PVE). The operation mortality (28) (first operation, no concomitant procedures) adds up to 1.4%, and is determined primarily by the times of aortic cross-clamping and cardiopulmonary bypass (29).

In flight medicine, TE is the most dreaded complication because of a potential sudden incapacitation, whereas SVD, NSD and PVE can, by adequate monitoring (echocardiography every 6-12 months), be discovered early in a still compensated condition with regards to a reoperation schedule. As noted by Carrier et al. (17), the 10-year-period without TE was approximately 91 ± 3% for the Carpentier-Edwards biological valve, freedom from PVE was 95 ± 2%, for SVD 92 ± 3%, and 93 ± 3% of patients avoided reoperation. The JAR 1% rule was respected in all four categories.

Jamieson et al. (27) reported similar results, with all valve-related problems being linear at 4.5% per patient-year (pt-yr), and all fatal complications at 0.9% per pt-yr. Conditional reoperations for SVD were performed at 1.2% per pt-yr, SVD without subsequent operation at 1.11% per pt-yr, NSD at 0.25% per pt-yr, TE at 1.21% per pt-yr, and PVE at 0.38% per pt-yr. Thus, these results approached the 1% JAR rule. It must be noted, however, that the TE rate was significantly higher when rhythm disturbances were present (atrial fibrillation 15.6% over 15 years, compared to 9.6% in sinus rhythm).

The life span of the bioprostheses implantation is determined by the risk of reoperation. A report from Zurich (28) which included 172 patients (average age at implantation 46 ± 13 years) showed the average life span of the aortic bioprostheses to be 10.4 ± 4.3 years. Moreover, no significant differences were identified among the different types of bioprosthesis. The average period until SVD develops depends also on the patient's age at the time of implantation (30). The interval between the first symptoms of degeneration of an aortic bioprosthesis and the time of reoperation was 8 ± 6 months. The most frequent reason for acute operation was the acute rupture of a cusp of the bioprosthesis, with hospitalization in an intensive care unit. The 30-day mortality amounted to 5.2% (elective 1.4%, acute 22.6%). The independent intraoperative risk factors for death in reoperation were: acute intervention, heart disease acquired during the interval, and a higher transvalvular gradient.

The life expectancy of a young patient who has received a biological valvular prosthesis is decisively affected by the risk of reoperation. Thus, the reduction of reoperative mortality is necessary, and can be enhanced by an early re-assessment (on average, at six months from the first symptoms until relevant deterioration of the valve). Both, early and elective reoperation leads to a reduction in the life span of the valves at an average of six months, but reduces in particular the operation mortality to 1.4%, which corresponds to the value of the primary operation (28).

After AVR, the risk of TE is highest during the first six months after surgery, and remains constant thereafter for the following five years. On average, the risk of TE from the second to the fifth postoperative year adds up to 0.5-1% per pt-yr (31,32). Aggressive postoperative management, as well as closer control intervals (of at least every 12 months in patients aged <35 years) are recommended from the fifth postoperative year onwards (32).

European legislation considerations

In Europe, the JAA legislation (14) (JAR-FCL 3, section 1 Requirements, Appendix 1 to subpart B & C, paragraph 9c Valvular Surgery, page 4) applies, which states the following requirements for re-certification after valvular surgery:

1. Applicants with implanted mechanical valves shall

be assessed as unfit
2. Asymptomatic applicants with a tissue valve who at least six months following surgery shall have satisfactorily completed investigations which demonstrate normal valvular and ventricular configuration and function may be considered for a fit assessment by the Aeromedical Section (AMS) as judged by:

(i) A satisfactory symptom-limited exercise electrocardiogram (ECG) to Bruce Stage IV or equivalent, which a cardiologist who is acceptable to the AMS interprets as showing no significant abnormality. Myocardial scintigraphy/stress echocardiography shall be required if the resting ECG is abnormal and any coronary artery disease has been demonstrated (see also paragraphs 5, 6 and 7 of Appendix 1 to subparts B & C (14));

(ii) A two-dimensional (2D) Doppler echocardiogram showing no significant selective chamber enlargement, a tissue valve with minimal structural alterations and with a normal Doppler blood flow, and no structural or functional abnormality of the other heart valves. The left ventricular fractional shortening shall be normal;

(iii) The demonstrated absence of coronary artery disease unless satisfactory revascularization has been achieved (defined as: no stenosis >50%; more than two stenoses between 30% and 50% shall not be acceptable; an untreated stenosis >30% in the left main or proximal left anterior descending coronary artery shall not be acceptable);

(iv) The absence of any requirement for cardioactive medication;

(v) Follow up with exercise ECG and 2D echocardiography, as necessary, will be determined by the AMS.

A Class 1 fit assessment shall require a multi-pilot (Class 1 OML) limitation. A fit assessment for Class 2 applicants may be applicable without a safety pilot (Class 2 OSL) limitation.

Conclusions and recommendations for flight licensing in Europe

Asymptomatic pilots with a tissue valve who, at least six months following surgery, have satisfactorily completed investigations demonstrating normal valvular and ventricular configuration and function, may be considered for a fit assessment by the AMS (14) (JAR-FCL 3, section 1 Requirements, Appendix 1 to subpart B & C, paragraph 9c, Valvular Surgery, page 4). Therefore, license renewal can be considered from the sixth postoperative month onwards. The licensing restrictions must exclude: +Gz-straining conditions over +3 Gz, and ejection seat aircraft in military aviation. A class 1 fit assessment require a multi-pilot (Class 1 OML) limitation. A fit assessment for Class 2 applicants may be applicable without a safety pilot (Class 2 OSL) limitation.

Communication and coordination between the cardiac surgeon and the AME in charge of the diseased pilot is of central importance. The implanting surgeon must assess the particular needs of pilots, in order to determine which valve is the best implanted, and to select the valve with the best hemodynamic profile under high-output conditions. Nowadays, the best flow profiles under high-output conditions seem to be obtained with pericardial or stentless valves (16,23). Rhythm disturbances during the first six postoperative months are the most important prognostic factor for sudden incapacitation, such as TE. For up to five years postoperatively, the risk of sudden incapacitation is low enough to fulfill the JAR 1% rule.

The prosthetic valve must be assessed echocardiographically at six-month intervals during the first year, and then annually, in order to provide a close monitoring of the evolution of prosthetic valve function, the flow pattern through the valve, the aortic diameter, the dimensions of the chambers, the left ventricular muscle mass, the left ventricular ejection fraction, and any rhythm disturbances (2). Such an assessment must be conducted by a cardiologist who is acceptable to the AMS, and must include a 48 h ECG record.

The early detection of SVD and rhythm disturbances are determinant for flight license renewal and any scheduling of reoperation. A pre-emptive timing when reoperation is indicated is recommend, without waiting for clinical manifestations of structural valve disease.

The behavior of prosthetic valves under high-flow conditions, as encountered in pilots and athletes, the therapeutic options at time of initial surgery, and the timing of reoperation, will require further investigation and research.

References

1. Fedak P, Verma S, David TE, Leask RL, Weisel RD, Butany J. Clinical and pathophysiological implications of a bicuspid aortic valve. Circulation 2002;106:900-904
2. Burks JM, Illes RW, Keating EC, Lubbe WJ. Ascending aortic aneurysm and dissection in young adults with bicuspid aortic valve: Implications for echocardiographic surveillance. Clin Cardiol 1998;21:439-443
3. Vahanian A, Baumgartner H, Bax J, et al. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J 2007;28:230-268
4. Ergin MA, Spielvogel D, Apaydin A, et al. Surgical treatment of the dilated ascending aorta: When and how? Ann Thorac Surg 1999;67:1834-1839

5. Bonow RO. Bicuspid aortic valves and dilated aortas: A critical review of the ACC/AHA practice guidelines recommendations. Am J Cardiol 2008;102:111-114
6. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to revise the 1998 guidelines for the management of patients with valvular heart disease). Endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol 200823;52:e1-e142
7. Bonow RO, Carabello BA, Chatterjee K, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing Committee to Revise the 1998 guidelines for the management of patients with valvular heart disease) developed in collaboration with the Society of Cardiovascular Anesthesiologists endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. J Am Coll Cardiol 2006;48:e1-e148
8. Prêtre R, Kadner A, Dave H, Bettex D, Genoni M. Tricuspidisation of the aortic valve with creation of a crown-like annulus is able to restore a normal valve function in bicuspid aortic valves. Eur J Cardiothorac Surg 2006;29:1001-1006
9. Anderson RH. Demystifying the anatomic arrangement of the aortic valve. Eur J Cardiothorac Surg 2006;29:1006-1007
10. Hardy J, Leonard F. Aortic valve replacement in a United States Air force Pilot: Case report and literature review. Aviat Space Environ Med 1997;68: 221-224
11. Joint Aviation Authorities (JAA). Manual of Civil Aviation Medicine. 2009 [cited 2009 Sept. 12]; Available from: http://www.jaa.nl/licensing/JAA%20Manual%20of%20Civil%20Aviation%20Medicine%20Amdt%206.pdf
12. International Civil Aviation Organization (ICAO). Manual of Civil Aviation Medicine, Part I Licensing Practices - Preliminary Edition. 2008 [cited 2009 Sept. 12]; Available from: http://www.icao.int/icaonet/dcs/8984/8984_Part_1_en.pdf
13. International Civil Aviation Organization (ICAO). Manual of Civil Aviation Medicine, Part III Medical Assessment - Preliminary Edition. 2008 [cited 2009 Sept. 12]; Available from: http://www.icao.int/icaonet/dcs/8984/8984_Part_3_en.pdf
14. Joint Aviation Authorities (JAA). Joint Aviation Requirements Flight Crew Licensing (Medical) JAR-FCL 3. 2006 [cited 2009 Sept. 12]; Available from: http://www.jaa.nl/publications/jars/606984.pdf
15. von Segesser LK. Personal communication, 2002
16. Pibarot P, Dumesnil JG. Prosthetic heart valves: Selection of the optimal prosthesis and long-term management. Circulation 2009;119:1034-1048
17. Carrier M, Pellerin M, Perrault LP, et al. Aortic valve replacement with mechanical and biologic prostheses in middle-aged patients. Ann Thorac Surg 2001;71:253-256
18. Hall RJ. Aortic valve disease. Eur Heart J 1984;5(Suppl.A):135-139
19. Jamieson WR, Janusz MT, MacNab J, Henderson C. Hemodynamic comparison of second- and third-generation stented bioprostheses in aortic valve replacement. Ann Thorac Surg 2001;71(5 Suppl.):S282-S284
20. Peteiro J, Campos VV, Valle J, Alvarez N, Castro-Beiras A. Hemodynamic comparison by Doppler echocardiography of valves in the aortic position: Value of the continuity equation to assess prosthetic dysfunction. Echocardiography 1998;15:325-336
21. Silberman S, Shaheen J, Merin O, et al. Exercise hemodynamics of aortic prostheses: Comparison between stentless bioprostheses and mechanical valves. Ann Thorac Surg 2001;72:1217-1221
22. Puvimanasinghe JP, Steyerberg EW, Takkenberg JJ, et al. Prognosis after aortic valve replacement with a bioprosthesis: Predictions based on meta-analysis and microsimulation. Circulation 2001;103: 1535-1541
23. Fries R, Wendler O, Schieffer H, Schafers HJ. Comparative rest and exercise hemodynamics of 23-mm stentless versus 23-mm stented aortic bioprostheses. Ann Thorac Surg 2000;69:817-822
24. Marquez S, Hon RT, Yoganathan AP. Comparative hydrodynamic evaluation of bioprosthetic heart valves. J Heart Valve Dis 2001;10:802-811
25. Milano AD, Blanzola C, Mecozzi G, et al. Hemodynamic performance of stented and stentless aortic bioprostheses. Ann Thorac Surg 2001;72:33-38
26. Nistri S, Sorbo MD, Marin M, Palisi M, Scognamiglio R, Thiene G. Aortic root dilatation in young men with normally functioning bicuspid aortic valves. Heart 1999;82:19-22
27. Jamieson WR, Janusz MT, Burr LH, Ling H,

Miyagishima RT. Carpentier-Edwards supraannular porcine bioprosthesis: Second-generation prosthesis in aortic valve replacement. Ann Thorac Surg 2001;71(5 Suppl.):S224-S227
28. Vogt P, Brunner-LaRocca H-P. Timing of reoperation of degenerated aortic and mitral bioprostheses. Z Kardiol 2001;90(Suppl.6):70-74
29. Vogt P, Brunner-LaRocca H-P. Long-term results of the surgical treatment in acute aortic valve endocarditis. Z Kardiol 2001;90(Suppl.6):27-34
30. Corbineau H, De La Tour B, Verhove JP, Langanay T, Lelong B, Leguerrier A. Carpentier-Edwards supraannular porcine bioprosthesis in aortic position: 16-year experience. Ann Thorac Surg 2001;71(5 Suppl.):S228-S231
31. Parker D. Long-term morbidity and mortality after aortic and mitral valve replacement with tissue valves and certification to fly. Eur Heart J 1988;9(Suppl.G):153-157
32. Fromer M, Egloff L, Turina M, Rothlin M. Replacement of the aortic valve with a bioprosthesis: 5-year surgical results. Schweiz Med Wochenschr 1988;118:313-318