Open Access | Original Research
Journal of Heart Valve Disease, 29(1), 2024 | PP: 06– 14
https://doi.org/10.36923/jhvd.v29i1.206

Patient-Prosthesis Mismatch Rate When Theoretical Ideal Body Weight Is Taken Into Account

Mirko Muretti[1], Enoch Akowuah[2], Andrew Goodwin[3]

Article History:

Received: 02-05-2024
Accepted: 11-06-2024
Publication: 15-06-2024

Cite this article as:

Muretti, M., Akowuah, E., & Goodwin, A. (2024). Patient-Prosthesis Mismatch Rate When Theoretical Ideal Body Weight Is Taken Into Account. *Journal of Heart Valve Disease,* 29(1). 6-14. doi.org/10.36923/jhvd.v29i1.205

Corresponding Author(s):

Mirko Muretti
The James Cook University Hospital, United Kingdom. Email: mirkomuretti@hotmail.com

Abstract: Objectives: This study aimed to examine whether the projected patient-prosthesis mismatch (PPM) rate calculated using the ideal body weight of patients can theoretically show a significant improvement compared to the actual rate of PPM conventionally calculated with the actual body weight of patients. **Methods:** We retrospectively analysed 2827 patients who underwent aortic valve replacement over 10 years. The rate of PPM was evaluated by measuring the iEOA using the body weight of the patients at the time of the operation and their ideal body weight. The difference in PPM rate was compared using the chi-square test; additionally, a P value < 0.05 was considered significant. **Results**: We observed a projected PPM rate of 50.2% with a moderate PPM of 45% and a severe PPM of 5.2% when the real body weight of the patients at the time of their operation was included in the calculus. Simulating a BMI of 22 for all patients, the rates of moderate and severe PPM decreased to 43.8% and 0.5%, respectively (P < 0.001). When simulating a lower BMI at 21, 20, and 19, there was a further significant reduction in moderate PPM at 38.8%, 33.4%, and 26.8%, respectively, and severe PPM at 0.2% and 0.1%, respectively (P < 0.001). **Conclusions:** A significant reduction in post-aortic valve replacement PPM was predicted when the ideal body weight of the patient was used instead of actual body weight, suggesting that pre- and postoperative weight loss programmes should be part of the strategy to reduce PPM.

Keywords: Patient-prosthesis mismatch, PPM; Aortic Valve Replacement; Indexed effective orifice area, iEOA; Index of effective orifice area, EOAi; Body surface area, BSA; Body mass index, BMI.

1. Introduction

The concept of patient-prosthesis mismatch (PPM) was initially introduced by Rahimtoola in 1978 when he described the observed discrepancy between the orifice of an implanted prosthesis and that of a normal human valve[1].

The best way to establish the relationship between the valve prosthesis orifice and the respective patient is to divide the effective orifice area (EOA) of the prosthesis with the body surface area (BSA) of the respective patient to calculate the indexed effective orifice area (iEOA). Indexed EOA (cm^2/m^2) = EOA (cm^2) / BSA of the patient (m^2).

PPM is considered severe when the iEOA is ≤ 0.65 cm^2/m^2 and moderate when the iEOA is between 0.85 and 0.66 cm^2/m^2. However, in patients with a body mass index (BMI) ≥30 kg/m^2 and a higher percentage of fat tissue with reduced metabolism, the Valve Academic Research Consortium 2 recommendations[2] suggested the use of lower thresholds of iEOA to identify PPM, such as moderate PPM when iEOA is between 0.70 and 0.60 cm^2/m^2 and severe PPM when iEOA is < 0.60 cm^2/m^2.

We know we live in an era when obesity and pre-obesity represent one of the largest global chronic health problems in adults. In general clinical practice, body fatness is estimated by BMI, which is calculated as measured body weight (kg) divided by measured height squared (m^2). It is agreed that in adults obesity is defined by a BMI of 30 kg/m^2 and pre-obesity by a BMI between 25 and 29.9 kg/m^2. Therefore, people with normal weight should have a BMI ranging between 18.5 to <25.0 kg/m^2 and a lower BMI cutoff is considered in Southeast Asia where a normal BMI can range between 18.5 and 22.9 kg/m^2.[3-5]

The aim of this study was to test whether the ideal body weight[6] of patients undergoing surgery could significantly decrease the PPM rate measured in real-life surgical activity. If this is the case, whenever we treat the patient preoperatively and postoperatively with the best medical treatment, we have to consider it mandatory to improve their body weight closer to their ideal body weight to avoid the detrimental consequences of PPM after aortic valve replacement (AVR).

[1]The James Cook University Hospital, United Kingdom. Email: mirkomuretti@hotmail.com
[2]The James Cook University Hospital, United Kingdom. Email: enoch.akowuah@nhs.net
[3]The James Cook University Hospital, United Kingdom. Email: andrew.goodwin1@nhs.net

2. Patients and Methods

The electronic database recording the data regarding cardiac surgery activity at our institute was interrogated and we retrospectively reviewed 2827 patients who underwent AVR (isolated or combined with other operations) from April 2011 to April 2021 at The James Cook University Hospital, The United Kingdom. We included isolated AVR and combined AVR with coronary artery bypass grafting, other valve operations, and aortic root or ascending aorta operations. The effective orifice area values of the prosthetic valves were obtained from the literature.[7-11]

Taking into account a specific patient who underwent AVR, it was assumed that EOA is a constant related to a specific implanted prosthesis, while BSA can be measured at the time of surgery and an ideal BSA calculated considering the hypothetical ideal body weight of the patient. In fact, BSA is generally derived according to the Dubois formula[12]:

$$\text{BSA (m}^2\text{)} = \text{weight (kg)}^{0.425} \times \text{height (cm)}^{0.725} \times 0.007184.$$

Therefore, considering that the height of the patient is fixed, the only variable that could change over time in that equation is the weight of the patient. Subsequently, body weight at the time of surgery and then the supposed ideal body weight of the patient can be included in the EOA calculus. The ideal body weight of the patients was obtained through the universal body weight equation proposed by Peterson et al.[6]:

$$\text{Ideal weight (kg)} = 2.2 \text{ x BMI} + 3.5 \text{ x BMI x (height metre - 1.5 metre)}.$$

Continuous variables were summarised as mean ± standard deviation (SD) or median and interquartile range (IQR) when appropriate. Categorical variables were summarised as absolute numbers and percentages. The chi-square test was used for the comparison of categorical variables; Furthermore, a *P* value > 0.05 was defined as not significant. JASP Team (2024). JASP (Version 0.18.3) [Computer software] was used for data analysis.

On 22 December 2021, this study was approved by the Health Research Authority (HRA). IRAS ID:309684; REC reference:21/HRA/5672. Informed consent was not required due to the retrospective nature of the study.

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

3. Results

A total of 2827 patients were retrospectively analysed. The main characteristics of the patients are summarised in Table 1.

Table 1: Characteristics of the patient

Patient characteristics	Study population (n=2827)
Age (y) (mean ± SD)	69 ± 11
Euroscore2 (median; IQR)	2.6; IQR 1.4 to 5.1
BSA m^2 (mean ± SD)	1.93 ± 0.22
BMI (kg/m^2) (mean ± SD)	29.2 ± 5.67
Creatinine (umol/L) (mean ± SD)	92 ± 49
Diabetes mellitus	636 (23%)
Diet	111 (4%)
Insulin	156 (6%)
Oral therapy	369 (13%)
Hypertension	1980 (70%)
COPD	520 (18%)
Left ventricle ejection fraction	
Good (LVEF > 50%)	2106 (75%)
Moderate (LVEF 31–50%)	511 (18%)
Poor (LVEF 21–30%)	170 (6%)
Very Poor (LVEF < 21%)	40 (1%)
Previous TIA	188 (6%)
Previous CVA	202 (7%)
Redo surgery	203 (7%)
Elective surgery	1929 (68%)
Urgent surgery	837 (30%)
Emergency surgery	61 (2%)

Source: Electronic database at The James Cook University Hospital

The mean age of the patients was 69 ± 11 years; the mean BSA of the patients was 1.93 ± 0.22; and the mean BMI was 29 ± 5.67. In particular, 33% of the patients were diabetic, 70% had hypertension, and 18% had COPD. The left ventricular ejection fraction was less than normal in 25% of the patients, and 13% had a history of

TIA/CVA. Most of the patients underwent elective surgery (68%), and 7% of the patients underwent a re-operation.

Different mechanical prostheses and bioprostheses were used over a ten-year period (Table 2).

Table 2: List of implanted prosthetic valves

Prosthetic valve name	Frequency	%
3f Enable sutureless	16	0.6%
CEBP	162	5.7%
Crown PRT	6	0.2%
Fitline	38	1.3%
Hancock Cinch II	1215	43.0%
Hancock Ultra	231	8.2%
Inspiris	6	0.2%
Magna	72	2.5%
Magna Ease	95	3.4%
Masters HP	78	2.8%
Masters Series	234	8.3%
Mitroflow	8	0.3%
Mosaic	20	0.7%
Mosaic Ultra	14	0.5%
On-X	6	0.2%
Perceval Aortic Valve	141	5.0%
Perimount	98	3.5%
Perimount RSR	40	1.4%
Regent	87	3.1%
Slimline	218	7.7%
St Jude Epic Supra	9	0.3%
Trifecta	33	1.2%
Total	2827	100%

Source: Electronic database at The James Cook University Hospital

A bioprosthesis was implanted in 77% of the patients, and the most common valve size was 23 mm and 25 mm in 31% and 28% of the patients, respectively (Table 3).

Table 3: Prosthetic valve size and type

Prosthetic valve size	
19	162 (6%)
21	597 (21%)
23	876 (31%)
25	794 (28%)
27	319 (11%)
29	79 (3%)
Prosthetic valve type	
Mechanical prosthesis	661 (23%)
Bioprosthesis	2166 (77%)

Source: Electronic database at The James Cook University Hospital

In this cohort of 2827 patients who underwent surgery over a 10-year time frame, we experienced a projected PPM rate of 50.2%, with moderate PPM at 45% and severe PPM at 5.2%. We speculated that if patients had undergone surgery with their ideal body weight, they could experience a significant drop in the projected PPM rate. When we calculated the projected PPM assuming that all patients in our cohort ideally had a BMI of 22, there was a 5.9% decrease in total PPM, the moderate PPM rate decreased from 45% to 43.8% and severe PPM decreased from 5.2% to 0.5%. With a BMI of 21, the rate of moderate PPM decreased from 45% to 38.8% and severe PPM decreased from 5.2% to 0.2%. With a BMI of 20, the rate of moderate PPM decreased from 45% to 33.4% and severe PPM decreased from 5.2% to 0.1%. Finally, with a BMI of 19, the moderate PPM rate decreased from 45% to 26.8% and the severe PPM from 5.2% to 0.1%. (Table 4).

Table 4: Percentage of PPM at different BMI.

Actual BMI at surgery		
No PPM %	Moderate PPM %	Severe PPM %
1418 (49.8%)	1266 (45%)	143 (5.2%)
Theoretical BMI 22		
No PPM %	Moderate PPM %	Severe PPM %
1575 (55.7%)	1239 (43.8%)	13 (0.5%)
Theoretical BMI 21		
No PPM %	Moderate PPM %	Severe PPM %
1723 (61%)	1098 (38.8%)	6 (0.2%)
Theoretical BMI 20		
No PPM %	Moderate PPM %	Severe PPM %
1879 (66.5%)	944 (33.4%)	4 (0.1%)
Theoretical BMI 19		
No PPM %	Moderate PPM %	Severe PPM %
2066 (73.1%)	758 (26.8%)	3 (0.1%)

The chi-square test showed a significant reduction in PPM ($P < 0.001$).

The magnitude of the drop in the predicted PPM assuming a progressively smaller BMI is better shown in figure 1.

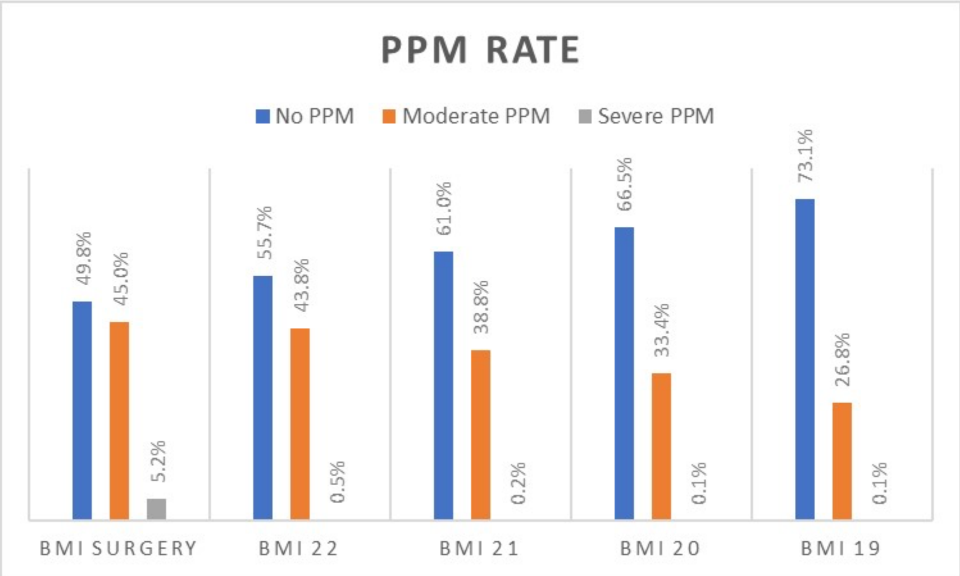

Figure 1: patient-prosthesis mismatch rate. The chi-square test showed a significant reduction in PPM ($P < 0.001$).

4. Discussion

Aortic valve replacement with a prosthesis has been performed for decades, drastically changing the expected life expectancy of patients with aortic valve disease[13].

Despite the acknowledged step forward in the field of manufacturing valve prostheses, it is still a matter of fact that prostheses are still no equal to native valves in terms of performance. One of the routine problems that a cardiac surgeon faces during aortic valve replacement is the possible PPM due to the small EOA of the implanted prosthesis relative to a patient with a large body size.

This condition was first described by Rahimtoola in 1978[1], who emphasised that a mismatch could be present when the area of the implanted prosthesis is smaller than that of a normal human valve. This mismatch could be severe and cause symptoms worse than those present before the operation.

In fact, the area of a normal aortic valve area is 3–4 cm^2 and all prostheses have an *in vitro* orifice area smaller than that of a normal human valve[7-11]. However, the relationship between the transvalvular gradient and the valve area is curvilinear, and the gradient rises dramatically only when the valve area is less than 35% of a normal valve[14]. This means that close to that threshold, a small increase in the valve area can drastically reduce the gradient despite the presence of a degree of mismatch between the patient and the prosthesis.

When it comes to evaluating the size of a valve prosthesis, the EOA is the best parameter that can be compared with the body size of the patient by measuring the BSA to predict the hemodynamic performance of that specific prosthesis in that specific patient.

Other parameters, such as the internal orifice area (IOA) or geometric area (GOA), are not representative of the real area available for trans-prothesis flow. In fact, the IOA does not account for the space occupied by the leaflets, and the GOA does not account for the flow contraction coefficient given by the EOA/GOA ratio, which varies from 0.70 to 0.90. Finally, the EOA *in vivo* that represents the functional area is smaller than the GOA due to the flow contraction phenomenon, and the transvalvular pressure gradients are more closely related to the EOA than to the GOA[15].

As described by Pibarot et al.[9], iEOA is the only parameter that shows a consistent correlation with the post-operative transprosthesis gradient. This correlation is curvilinear, as the transprosthesis gradient increases exponentially when the iEOA is 0.85 cm^2/m^2. Therefore, PPM was accepted to be moderate when the iEOA is between 0.75 and 0.85 cm^2/m^2 and severe when < 0.65 cm^2/m^2.

The incidence of PPM at our institute is 50.2% (moderate PPM 45% and severe PPM 5.2%), which is in line with the results described in the literature stating an incidence of moderate PPM between 20 and 70% and that of severe PPM between 2 and 11%[16-17].

Various studies have described the deleterious effects of PPM post-AVR. Del Rizzo et al.[18] showed that after three years after aortic valve replacement with porcine bioprosthesis, the mass index of the left ventricle (LV) decreased by 23% among patients whose iEOA was > 0.8 cm^2/m^2, instead of only 4.5% when the iEOA was < 0.8 cm^2/m^2. Pibarot et al.[7] observed that postoperative PPM can reduce improvement in symptoms due to a low regression of LV hypertrophy and is associated with shorter long-term survival. RAO et al.[19] showed that PPM with an EOA/BSA ratio <0.75 cm^2/m^2 results in significantly higher early and late mortality after bioprosthetic AVR (7.9% vs 4.6%, $P = 0.027$). Blais et al. highlighted that PPM is an independent risk factor for short-term mortality in patients undergoing AVR, with an increased risk of mortality by 10 times when the PPM was severe and 2 times with a moderate PPM. In addition, PPM is particularly harmful in patients with left ventricular dysfunction and, therefore, a more vulnerable heart[8]. Takagi et al.[20], Chen et al.[21] , and Head et al.[22], reported increases of 31%, 34% and 42%, respectively, in mid and late all-cause mortality in patients with any degree of PPM. A large meta-analysis by Dayan et al. showed that severe PPM has a significant impact on both perioperative and overall mortality, whereas moderate PPM has an impact only on perioperative mortality due to a possible vulnerability of the heart to some remaining afterload in the perioperative period[23]. A more recent meta-analysis found that moderate PPM was significantly associated with increased mortality, not only in the perioperative period but also in the early, mid-and long-term follow-up. Moreover, severe PPM was found to have an even greater negative impact on mortality than moderate PPM17-24. Finally, the incidence of PPM appears to be higher when AVR is performed using a bioprosthesis[25,26].

Based on this evidence, PPM should be avoided whenever possible, and we speculated that a significant reduction in PPM could be achieved if patients undergo surgery with a body weight closer to their ideal body weight. Therefore, for the first time in the literature, we simulated a real-world cohort of patients who underwent isolated AVR or combined AVR using a variety of bioprostheses and mechanical prostheses over 10 years and demonstrated their results with a BMI value of 22, and subsequently with BMI values of 21, 20, and 19.

Comparison between the iEOA calculated with the ideal body weight of the patients and the iEOA measured using the real body weight of the patients at the time of their operation showed a decrease in the PPM rate that was considered significant using the chi-square test (Table 4).

Although PPM can be avoided using surgical procedures for aortic root enlargements that allow the implantation of a larger aortic valve prosthesis in an aortic annulus judged to be too small in relation to the patient BSA[27-29], our study showed that the same target could potentially be achieved through mindful management of preoperative and postoperative body weight of patients undergoing AVR. Therefore, when trying to lose weight to get closer to the ideal body weight of a patient, it should be considered with the aim of reducing the rate of PPM and, hence, improving the short- and long-term outcomes of the patients after AVR.

The main limitation of this study is that the simulated calculus was attained by considering the projected PPM derived from the EOAs extrapolated from the literature, in contrast with the measured PPM.

In fact, there are ambivalent results on how much PPM can negatively affect the outcomes. Additionally, although the severity of PPM appears to be associated with low symptomatic improvement caused by low LV mass regression, impaired hemodynamics at rest and during exercise, and more cardiac events after AVR, other authors, such as Hofmann et al. showed that there was no impact on short-term survival due to PPM present in 93.8% of their 632 patients who received a stented biological aortic prosthesis[16]. Moreover, in univariate analysis, PPM was not an independent predictor of decreased survival at 30 days. Furthermore, in a mean long-term follow-up of approximately two decades, moderate and severe PPM were not independent predictors of decreased long-term survival[30].

The contradictory results of these studies can be due to the inaccuracy of a projected PPM compared to a measured PPM as was demonstrated in the Perigon trial[31] where it was striking to see that the difference between the minimum and maximum measured EOA of the new bovine stented Avalus aortic valve bioprosthesis was 0.91 cm^2 for size 19 mm, 1.22 cm^2 for size 21 mm, 1.48 cm^2 for size 23 mm, 1.63 cm^2 for size 25 mm, and 1.61 cm^2

for size 27 mm. Finally, the Perigon trial highlighted that the use of an iEOA chart led to an incorrect prediction of PPM in 30% of patients and severe PPM in 22% of patients. Due to this weak correlation between the normal reference values of EOA and the actual measured EOA, the projected PPM derived from an iEOA chart does not seem to accurately reflect a prosthetic valve too small for a certain body size. The authors recommended that studies that analyse the effect of PPM on survival should be based only on individually measured EOA values and that surgeons and cardiologists should not use iEOA charts to predict PPM.

This concept was already stressed by Florath et al., who demonstrated that a severe PPM estimated by EOA measured within 10 days after surgery was an independent risk factor for survival time, while projected iEOA determined at surgery does not sufficiently predict a mismatch[32].

The reason behind this difference between the projected and measured PPM is that when a prosthesis valve is implanted in a patient with a larger left ventricle outflow tract (LVOT), the EOA tends to be smaller than the GOA of the prosthesis, and when the same-sized prosthesis is implanted in a patient with a smaller LVOT, the EOA and GOA become similar. The explanation for this phenomenon is the flow convergence due to the principle of fluid dynamics.

At this point, it is apparent that the same prosthesis may result in different EOAs, depending on the aortic valve annulus / LVOT ratio. In other words, the same prosthesis could present different EOAs depending on the extent to which the flow was compressed by passing through the LVOT of a specific patient and then through the prosthetic valve. Thus, we can obtain different hemodynamics in different patients receiving the same prosthesis.

The direct conclusion is that EOA is a patient-specific measure of hemodynamic performance and not a valve-specific value. Therefore, theoretically, the EOA calculated in a patient cannot be transferred to another with the same prosthesis, in contrast to what is suggested by the globally available EOA charts proposing a "projected" EOA apparently useful for addressing PPM.[33] However, it has recently been seen that measured PPM could overestimate the incidence of severe PPM compared to projected PPM, but it was also associated with a worse outcome[34].

5. Study limitations

This study has some limitations. Firstly, the retrospective and observational nature of the investigation can cause bias. Secondly, the study was carried out in a single centre, reporting only the results of our department. Finally, we base our study on the projected PPM, while some authors stress the importance of considering the measured PPM because an EOA calculated in a patient potentially cannot be transferred to another patient with the same prosthesis. Therefore, some evidence discourages the use of iEOA charts to predict PPM.

6. Conclusions

PPM is known to worsen the results after AVR. Accepting the limitation due to the use of projected PPM, for the first time this study simulated the theoretical advantage of losing body weight by reducing BSA to significantly prevent PPM in a real-world cohort of patients who underwent AVR. The results of our study could encourage the introduction of a formal preoperative and postoperative weight loss programme as a possible strategy to reduce PPM in cardiac surgery. Cardiac rehabilitation with customised programmes for each patient can favour weight loss by promoting better lifestyle-related behaviours in addition to the conventional exercise program.[35-39]

However, currently, there is a lack of studies focused on a weight loss programme in patients waiting for heart operations specifically AVR, and considering the challenge of losing weight in symptomatic patients waiting for AVR and after AVR, further research on this topic is much awaited.

Acknowledgement Statement: The authors would like to thank the reviewers for providing comments in helping this manuscript to completion.

Conflicts of Interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT Author contribution statements: Author 1 contributes to conceiving, designing, conducting the research, analyzing the data, drafting the initial manuscript, methodology and data analysis, collecting data, drafting, formatting, and analysing, Author 3 continues into Investigation and Author 2 also contributes to Investigation, Visualization, and Writing – Review & Editing.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Data Availability Statement: Data is available at request. Please contact the corresponding author for any additional information on data access or usage.

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About the Author (s)

Mr Mirko Muretti is a Cardiac Surgeon who started is training at Istituto Clinico Humanitas in Milan, Italy. He had a fellowship in one of the largest heart centres in the Netherlands, the St. Antonius Hospital. Before moving to the United Kingdom he had further experience abroad in Switzerland at Istituto Cardiocentro Ticino. Then he started as a clinical observer in Cardiothoracic Surgery at the Royal Brompton Hospital to carry on as a senior fellow in cardiothoracic surgery at Oxford University Hospital and then The James Cook University Hospital. His main area of interest is minimally invasive surgery

Prof. Enoch Akowuah underwent specialist cardiac surgery training in a number of UK cardiac surgery units including Papworth Hospital in Cambridge, Sheffield, Bristol and Plymouth before moving to Melbourne Australia, for a one-year advanced cardiac surgery fellowship. An award from the Society of Cardiothoracic Surgeons for Great Britain and Ireland funded this fellowship.

At present his main area of practice remains adult cardiac surgery with large experience in minimally invasive surgery at The James Cook University Hospital. He is also focused on research being the Chief investigator of The UK Mini Mitral Trial

Mr Andrew Goodwin is a consultant specialising in adult cardiac surgery, minimally invasive valve surgery and surgery of the thoracic aorta. He was training at St Mary's Hosp (MB BS), Imperial College/National Heart Lung Institute (PhD), Papworth/Brompton/Norwich NTN registrar rotation and he achieved the following qualifications and accreditations: MB BS 1990, FRCS 1995, FRCS(CTh) 2002, PhD 2007

At present his main area of practice remains adult cardiac surgery at James Cook University Hospital, United Kingdom