The Effective Orifice Area/Patient Aortic Annulus Area Ratio: A Better Way to Compare Different Bioprostheses? A Prospective Randomized Comparison of the Mosaic and Perimount Bioprostheses in the Aortic Position

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Background and aim of the study: **The aim of this prospective, randomized study was to compare the hemodynamic performance of the Medtronic Mosaic and Edwards Perimount bioprostheses in the aortic position, and to evaluate prosthesis-specific differences in valve sizing and valve-size labeling.**
Methods: **Between August 2000 and September 2002, 139 patients underwent isolated aortic valve replacement (AVR) with the Mosaic (n = 67) or Perimount (n = 72) bioprosthesis. Intraoperatively, the internal aortic annulus diameter was measured by insertion of a gauge (Hegar dilator), while prosthesis size was determined by using the original sizers. Transthoracic echocardiography was performed to determine hemodynamic and dimensional data. As the aim of AVR is to achieve a maximal effective orifice area (EOA) within a given aortic annulus, the ratio of EOA to patient aortic annulus area was calculated, the latter being based on annulus diameter measured intraoperatively.**
Results: **Operative mortality was 2.2% (Mosaic 3.0%; Perimount 1.4%; p = NS). Upsizing (using a prosthesis larger in labeled valve size than the patient's measured internal aortic annulus diameter) was possible in 28.4% of Mosaic patients and 8.3% of Perimount patients. The postoperative mean systolic pressure gradient ranged from 10.5 to 22.2 mmHg in the Mosaic group, and from 9.4 to 12.6 mmHg in the Perimount group; it was significantly lower for 21 and 23 Perimount valves than for 21 and 23 Mosaic valves. The EOA ranged from 0.78 to 2.37 cm^2 in Mosaic patients, and from 0.95 to 2.12 cm^2 in Perimount patients. When indexing EOA by calculating the ratio of EOA to patient aortic annulus area to adjust for variables such as patient anatomy and valve dimensions, there was no significant difference between the two bioprostheses.**
Conclusion: **Comparisons of absolute EOA values grouped by the manufacturers' valve sizes are misleading because of specific differences in geometric dimensions. The EOA:patient aortic annulus area ratio provides a new hemodynamic index which may facilitate objective comparisons between different valve types.**

The Journal of Heart Valve Disease 2004;13:382-389

In clinical series evaluating the hemodynamic performance of prosthetic valves in vivo, the pressure gradient and effective orifice area (EOA) - when determined using transthoracic echocardiography (TTE) - are the two most important indicators of prosthetic function. In general, results are presented in groups corresponding to the valve size as labeled by the prosthesis manufacturer and compared to other prostheses with the same labeled valve size. However, the discordance between true internal and external valve dimensions and the millimeter size with which a prosthesis is characterized by the manufacturer calls into question the value of comparisons of hemodynamic results between different prostheses based on valve-size groups. For example, the internal diameter of a Mosaic prosthesis labeled 21 by the manufacturer (Medtronic) is 18.5 mm (1), whereas that of a 21 Carpentier-Edwards Perimount (Edwards) is 20.0 mm (2). Thus, to allow methodically correct comparisons between various valve prostheses, a representative parameter - which is independent of valve-size groups - must be found to describe and compare prosthesis performance. Hence, two established bioprostheses were studied, the Medtronic Mosaic and Carpentier-

Presented at the Second Biennial Meeting of the Society for Heart Valve Disease, 28th June-1st July 2003, Palais des Congrès, Paris, France

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Edwards Perimount, with attention focused on the issues of hemodynamic performance, valve sizing, and valve-size labeling.

Clinical material and methods

Patients

Between August 2000 and September 2002, 139 patients diagnosed with aortic stenosis or mixed lesion of the aortic valve, who required valve replacement, entered the study. Patients with isolated aortic regurgitation, those who underwent replacement of more than one valve, or those who already had a pre-existing prosthetic valve in another position, were excluded. Patients undergoing other concomitant procedures were permitted to enter the study. After each patient's informed consent had been received, preoperative randomization was performed by blindly choosing a closed envelope, which contained a note for one of the study valves. Thus, in total 67 patients received a Mosaic (Medtronic) bioprosthesis, and 72 received a Carpentier-Edwards Perimount (Edwards) bioprosthesis.

The study was approved by the institutional ethics committee.

Bioprostheses

The Mosaic bioprosthesis is a stented porcine heart valve which is fixed with glutaraldehyde by using a combination of the zero-pressure and root-pressure methods to preserve the natural morphology and arrangement of the collagen and elastic fibers in the leaflets (3,4). In order to reduce calcification, the Mosaic tissue is treated with alpha-amino-oleic acid (AOA) (5-7). The Mosaic bioprosthesis has been in clinical use since 1994 (Europe) and 2000 (USA), respectively. Hemodynamic performance and freedom rates from adverse events have been found to be very satisfactory (8-12).

The Carpentier-Edwards Perimount bioprosthesis consists of stented bovine pericardium. The cusps are matched for thickness, and then treated with a surfactant to retard calcification. The Perimount received FDA approval in 1991, and long-term studies have constantly shown excellent hemodynamic and clinical results (13-18).

Surgical technique

Aortic valve replacement (AVR) was undertaken using standard cardiopulmonary bypass under mild hypothermia with cold crystalloid cardioplegia. After removal of the native aortic valve and decalcification of the aortic annulus and root, the internal diameter of the aortic annulus was measured by inserting a gauge (Hegar dilator) into the annulus (unit: 1 mm). The prosthetic valve size was then determined by using the original sizer provided by each manufacturer. The Mosaic valve is designed to allow for a complete

Table I: Patient preoperative data.

Parameter	Mosaic	Perimount	p-value*
No. of patients	67	72	
Age at implant (years)			0.361 (NS)
Mean ± SD	75.8 ± 5.3	75.0 ± 5.6	
Range	65.7-89.5	60.1-87.8	
Gender (%)			0.291 (NS)
Males	49.3	40.3	
Females	50.7	59.7	
Cardiac rhythm (%)			0.098 (NS)
Sinus rhythm	82.1	73.2	
Atrial fibrillation	10.4	14.1	
Heart block	3.0	2.8	
Paced rhythm	3.0	9.9	
NYHA class (%)			0.697 (NS)
I	0.0	0.0	
II	4.6	8.5	
III	80.0	69.0	
IV	15.4	22.5	
Aortic valve lesion (%)			0.576 (NS)
Isolated stenosis	40.0	44.9	
Stenosis and regurgitation	60.0	55.1	

*t-test for independent samples.
NS: Not significant.

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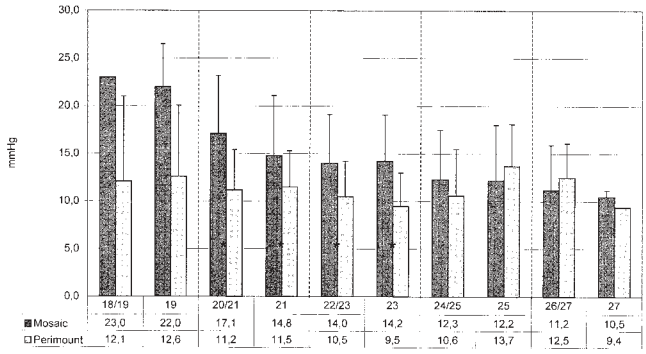

*Figure 1: Mean pressure gradient grouped by valve size and by aortic annulus diameter (*p <0.05).*

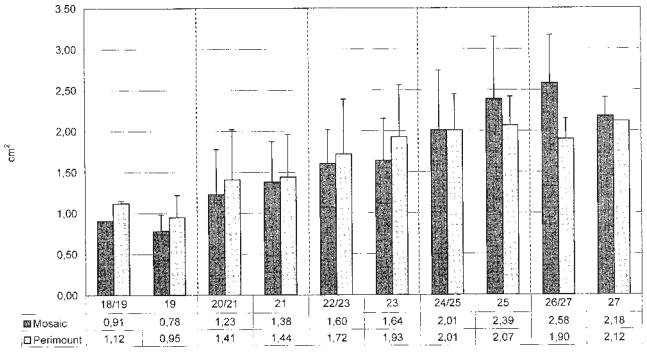

Figure 2: Effective orifice area (EOA) grouped by valve size and by aortic annulus diameter.

supra-annular implantation technique, which is possible because of the combination of a low-profile stent design and a construction such that stent material does not reach into the aortic annulus. The Perimount bioprosthesis is sized for, and implanted in, the intra-supra-annular position. There was no difference in the operative technique used for the two valve types, with non-everting mattress sutures being used in both cases.

Data acquisition and patient follow up

As the aim of AVR is to achieve a maximal EOA within a given aortic annulus, the ratio of EOA to patient aortic annulus area was calculated for the Mosaic and Perimount groups. Aortic annulus area was determined using the formula: area = $r^2 \times \pi$, with r = 0.5 × aortic annulus diameter (in cm), assuming that the aortic annulus area geometrically approaches a circle:

Effective orific fraction (EOF) annulus index = EOA (cm^2)/Aortic annulus area (cm^2)

Preoperative and operative data are summarized in Tables I and II. A *t*-test for independent samples did not reveal any significant differences between both samples, apart from valve-size distribution. The patient follow up included an examination by TTE preoperatively and within 10 days postoperatively.

Statistical analysis

Results were reported as mean ± SD. Statistical comparisons were performed using a *t*-test for independent samples, and a p-value <0.05 was considered to be statistically significant.

Results

The hemodynamic results, obtained by TTE, are listed in Table III. The mean pressure gradient, EOA and

Table II: Operative data.

Parameter	Mosaic	Perimount	p-value+
Valve size (labeled)			0.047
19	3	5	
21	18	25	
23	30	35	
25	14	6	
27	2	1	
Concomitant procedure (%)			0.802 (NS)
None	52.2	50	
CABG	43.3	47.2	
Other	4.5	2.8	
Aortic cross-clamp time (min)*			0.179 (NS)
Isolated procedures	60.0 ± 14.7	62.0 ± 15.4	
Combined procedures	80.9 ± 19.1	88.6 ± 26.3	

*Values are mean ± SD.
+t-test for independent samples.
CABG: Coronary artery bypass graft; NS: Not significant.

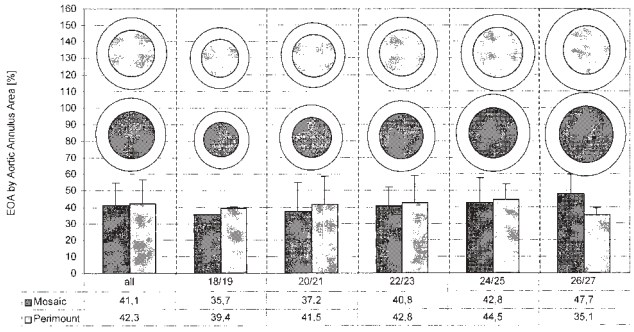

Figure 3: Ratio of effective orifice area (EOA) by aortic annulus area (%). The circles illustrate the proportion of the EOA within the aortic annulus area.

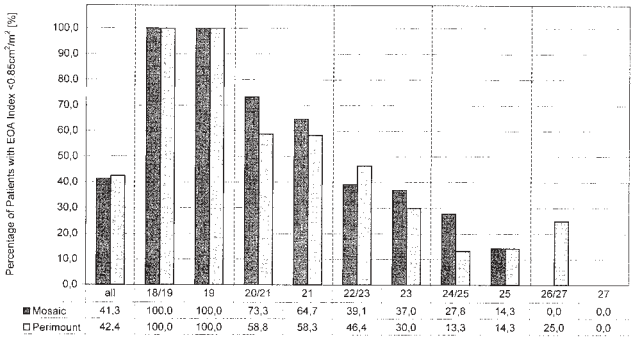

Figure 4: Percentage of patients with effective orifice area (EOA) index <0.85 cm^2/m^2.

EOA index (EOAI; calculated as EOA/body surface area (BSA)) were arranged according to valve sizes as provided by the manufacturer. The hemodynamic results of 10 patients were missing: in the Mosaic group, two patients were lost to follow up, and two died before the follow up examination. In the Perimount group, five patients were lost to follow up, and one patient died before follow up examination. Using a *t*-test for independent samples, there was a significant difference in mean pressure gradient in favor of the 21 and 23 Perimount bioprostheses when compared to the Mosaic valve. With regard to EOA and EOAI, the two bioprostheses did not differ significantly. When the hemodynamic results were separated into aortic annulus diameter groups (18/19 mm, 20/21 mm, 22/23 mm, 24/25 mm, 26/27 mm) rather than into labeled valve-size groups, there remained a significant difference in mean pressure gradients in patients with an aortic annulus of 20, 21, 22 and 23 mm receiving the Perimount bioprosthesis when compared to those receiving the Mosaic valve; however, there were no significant differences in terms of EOA and EOAI. These results are illustrated in Figures 1 and 2. When dividing the EOA by the patient's aortic annulus area (which is based on an intraoperatively determined aortic annulus diameter), the result indicates the percentage of the aortic annulus area which is used for blood flow. There was no significant difference between both prostheses with regard to this ratio (Fig. 3).

The comparison of intraoperatively measured internal aortic annulus diameter and finally implanted valve size as labeled by the manufacturer showed that upsizing was possible in 28.4% of Mosaic patients and 8.3% of Perimount patients. Upsizing implied that the labeled size of the implanted valve was larger than the measured internal aortic annulus diameter (Table IV). When comparing the Mosaic and Perimount groups by *t*-test for independent samples, there was a significant difference in the mean labeled valve sizes (Mosaic 22.8 mm, Perimount 22.3 mm), whereas there was no significant difference in the mean aortic annulus diameters (Mosaic 22.8 mm, Perimount 22.6 mm). A *t*-test for

Table III: Postoperative echocardiographic data.

Valve Size	Mean pressure gradient (mmHg)					Effective orifice area (cm^2)					Effective orifice area index (cm^2/m^2)[a]				
	Mosaic		Perimount		p-value*	Mosaic		Perimount		p-value*	Mosaic		Perimount		p-value*
	n	Mean	n	Mean		n	Mean	n	Mean		n	Mean	n	Mean	
19	3	22.0 ± 4.5	4	12.6 ± 7.5	-	3	0.78 ± 0.20	4	0.95 ± 0.27	-	3	0.35 ± 0.24	4	0.62 ± 0.18	-
21	17	14.8 ± 6.3	24	11.5 ± 3.8	0.045	17	1.38 ± 0.49	24	1.44 ± 0.52	NS	17	0.81 ± 0.30	24	0.85 ± 0.30	NS
23	27	14.2 ± 4.9	30	9.5 ± 3.5	0.000	27	1.64 ± 0.51	30	1.93 ± 0.63	NS	27	0.93 ± 0.31	30	1.05 ± 0.36	NS
25	14	12.2 ± 5.8	7	13.7 ± 4.4	NS	14	2.39 ± 0.76	7	2.07 ± 0.35	NS	14	1.26 ± 0.42	7	1.08 ± 0.16	NS
27	2	10.5 ± 0.7	1	9.4	-	2	2.18 ± 0.23	1	2.12	-	2	1.18 ± 0.11	1	1.14	-
All	63	14.2 ± 5.7	66	10.9 ± 4.2	0.000	63	1.71 ± 0.69	66	1.71 ± 0.62	NS	63	0.95 ± 0.38	66	0.95 ± 0.33	NS

*t-test for independent samples; if n <6, no *t*-test was performed.
EOA index: EOA/body surface area; NS: Not significant.

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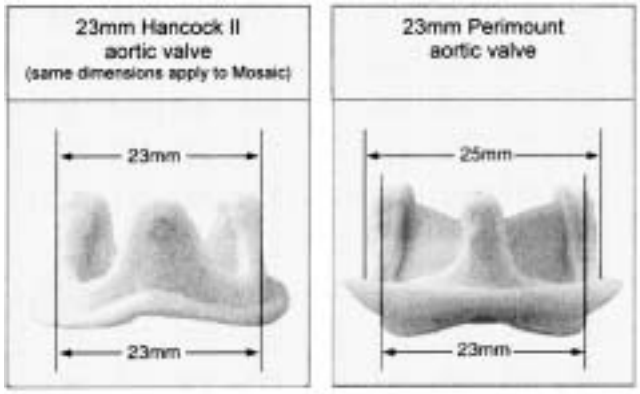

Figure 5: The geometric dimensions of the Mosaic and Perimount bioprostheses.

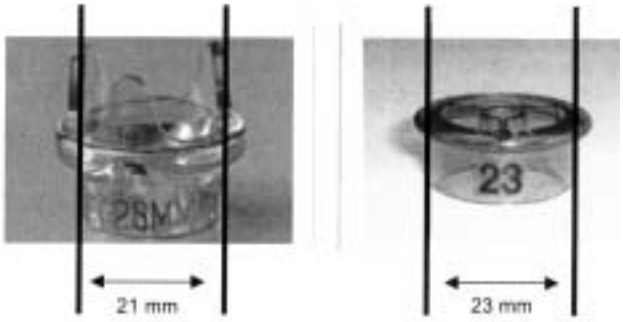

Figure 6: The original Mosaic (left) and Perimount (right) valve sizers for the corresponding valves labeled as 23.

dependent samples revealed a significant difference between mean labeled valve size (22.3 mm) and mean aortic annulus diameter (22.6 mm) in the Perimount group, whereas in the Mosaic group there was no significant difference (mean labeled valve size 22.8 mm, mean aortic annulus diameter 22.8 mm).

When focusing on patient-prosthesis mismatch (which is defined as the implantation of a prosthesis too small in relation to the patient's body surface area, and is represented by an EOA/BSA value <0.85 cm2/m2), a high percentage of patients with small valve sizes showed a mismatch, though this decreased in line with increasing prosthetic size. There was no significant difference between both bioprostheses in the incidence of patient-prosthesis mismatch (Fig. 4).

Discussion

The hemodynamic performance of the Mosaic and Perimount bioprostheses was very satisfactory, and the results of this investigational series corresponded to the outcomes of other reports for these prosthetic heart valves (8-18). There was a superiority of the 21 and 23 Perimount valve in terms of mean pressure gradient compared to the Mosaic valve, and in both valve groups there was a clear correlation between valve size and hemodynamic parameters. As expected, the mean pressure gradients decreased and EOAs increased with increasing valve size, and consequently as large a valve as possible should be implanted by the cardiac surgeon.

Table IV: Comparison of patient internal aortic annulus diameter and implanted valve size.

Valve size to annulus diameter	Proportion of implants (%)	
	Mosaic	Perimount
>	28.4	8.3
=	38.8	54.2
<	32.8	37.5

The insertion of an inadequately adapted prosthesis into a small anatomic site may result in postoperative and long-term complications, however, and new techniques were necessary to avoid patient-prosthesis mismatch, especially at sites with a small aortic annulus. The idea in constructing the Mosaic bioprosthesis was to combine a low-profile stent with its surgical placement on top of the annulus. This model minimizes impact on physiological flow patterns by the stent and allows the implantation of a larger valve. To evaluate the frequency of using a larger valve size than with conventional methods, the internal aortic annulus diameter was measured intraoperatively and compared with the finally implanted valve size as labeled by the manufacturer.

Upsizing was possible in 28.4% of Mosaic patients and 8.3% of Perimount patients. The higher percentage in the Mosaic group might indicate the advantage of using a complete supra-annular implantation technique with this valve, as compared to the Perimount. Nonetheless, upsizing was not possible in 71.6% of the Mosaic patients, mainly due to anatomic conditions and variations (e.g. a narrow aortic bulbus). The selection and implantation of a certain, manufacturer-labeled valve size based on anatomic measurements represents a technical error. To suggest that implanting a valve one size larger can be realized by use of a new technique does not provide information about the geometric diameters of the prosthesis, nor about any differences between two valve sizes. It would be more precise to say that the benefit of this new implantation technique was to achieve an increase in the EOA of a certain valve type, and to avoid erroneous information from the valve-sizing labels.

There is a guideline standard for determining labeled valve size, to which valve manufacturers and

the FDA adhere (ANSI/AAMI/ISO 5840) (19). The standard employed for stented tissue valves is the external diameter (tissue annulus diameter) of the valve where it is intended to meet with the diameter of the patient's annulus. However, the labeled valve size does not reflect the geometric dimensions of the sewing ring and stent of a prosthesis. As shown in Figure 5, the external stent diameter of the Perimount valve on the outflow side is larger than the external stent diameter of the Mosaic valve - 25 mm for the 23 Perimount, 23 mm for the 23 Mosaic. In contrast, the tissue annulus diameter is 23 mm for both valves, with a short stent portion of the Perimount valve reaching into the annulus. Thus, the low-profile design of the Mosaic bioprosthesis led to it being slightly smaller or narrower than the Perimount, yet with the same labeled valve size. The advantage of this narrowing process is that a 23 Mosaic valve, for example, can be implanted into a narrow aortic root and straight aortic bulbus. This is not possible with a 23 Perimount valve, as the external stent diameter is too large when compared with the anatomic conditions, it is larger in comparison with the prosthetic inflow diameter, and it is also larger compared to the Mosaic valve overall.

The fact that the Mosaic valve geometry is slightly smaller than the Perimount is one reason for the greater proportion of upsizing in the Mosaic group. Upsizing is also possible due to the construction of the original Mosaic sizer compared with the original Perimount sizer. Both sizers for the labeled valve size 23 are shown in Figure 6. The part of the Mosaic sizer which is inserted into the patient's aortic annulus must fit with the annulus diameter, but indicates the use of a bioprosthesis labeled 2 mm larger. The sizer for the 23 Mosaic valve consists of one side which is used for annulus measurement and fits an aortic annulus of 21 mm diameter, while the other side is a replica of the 23 Mosaic bioprosthesis. Thus, the cardiac surgeon tends to implant a bioprosthesis with a larger labeled valve size than the measured annulus. In contrast, the 21 Perimount sizer fits an aortic annulus of 21 mm diameter and implies the implantation of a Perimount bioprosthesis labeled 21. However, the use of a 23 Mosaic valve in a 21 mm aortic annulus, or a 21 Perimount valve in a 21 mm aortic annulus, must have neither advantage nor disadvantage for either bioprosthesis with regard to hemodynamic performance. As mentioned above, the internal diameters of Mosaic bioprostheses labeled 21 and 23 are 18.5 ± 0.5 m and 20.5 ± 0.5 mm respectively (1), whereas that of a 21 Perimount is 20.0 mm (2). These differences prohibit the association of hemodynamic data to labeled valve sizes, and also falsify comparisons between different valve types.

In the present study, the fact that a larger Mosaic bioprosthesis was implanted into a known annulus diameter more often than a larger Perimount bioprosthesis may simply be attributed to the smaller geometric dimension of the 21 Mosaic compared with the 21 Perimount. On the other hand, the significantly lower mean pressure gradients of the 21 and 23 Perimount valves in comparison to the Mosaic may be due to the larger internal diameter of the former. Because of these unclear and indefinite modes of interpretation, it is recommended that valve-size labeling be reconsidered. One way to solve this problem of valve size choice when using different valve types may be to use a new index of EOA:aortic annulus area ratio (see Fig. 3). A second approach would be to refer to the internal diameter of the aortic annulus for hemodynamic comparisons (as shown in Figs. 1 and 2). In the present authors' opinion, the fact that in the present study no significant difference was identified between EOA and EOA:annulus area ratio should not suggest that this new index is worthless. Rather, its value may be better used for comparisons of stented versus stentless valves, or of prostheses where supra-annular and intra-annular versions are available.

In conclusion, the hemodynamic performance of the Mosaic and Perimount bioprostheses was very satisfactory, and the present results were in agreement with those of other investigational series. There was a significant superiority of the 21 and 23 Perimount valves in terms of mean pressure gradient when compared to the Mosaic, though a direct comparison may be questionable with regard to the geometric differences of valves labeled as being of the same size. Hence, the introduction of hemodynamic parameters that are independent of valve size label is recommended, and this may be realized by using the EOA:aortic annulus area ratio, measured intraoperatively.

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Meeting discussion

DR. TIRONE DAVID (Canada): In your third conclusion, the gradient was less for 21 and 23, but not the same patients received 21 and 23 valves. In other words, when you implanted a 21 Perimount, you could have implanted a 23 Mosaic - so the situation is not comparable.

DR. W. B. EICHINGER (Munich, Germany): We also performed an analysis where we grouped the pressure gradient results by annulus diameter, and the results were similar to those I showed for the pressure gradient. There was also a significantly higher pressure gradient in the 21 and 23 Mosaic group. So there was no difference.

DR. DAVID: But the same patient who received a 21 Mosaic would not receive a 21 Perimount - they would have a 19 Perimount? Did I read that correctly?

DR. EICHINGER: It is not true for every patient - this upsizing was only possible in about one-third of the patients.

DR. LAWRENCE BURR (Canada): A brief comment on the sizing problem. The International Standards Organization is examining their standard 5840 for cardiac valves, and the working group, SC2WG1, is actively working on a draft international standard now, hopefully to be completed in September 2003. By 2004 this is hoped to be a new international standard, and part of it will include changing the definitions that you have presented today. You showed the picture of the schema of the prosthetic valve from the ANSI and the AAMI criteria, and it measured tissue annulus diameter. The new definition of tissue annulus diameter will not be the prosthetic valve - it will be the patient's annulus, because that is not the tissue annulus diameter, it is the manufacturer's. So the new definition of tissue annulus diameter will be what you find with the Hegar dilator or a plug gauge of some kind. Additionally, the valve will be sized by the manufacturer based on the position in which it is designed to be implanted - intra-annular, supra-annular - and also by the suture technique - everting, inverting, mattress - whatever the manufacturer decides. So these definitions will change, and we hope that they will be easier in the future, because we have all had this problem in the past of manufacturers' different sizes and their valve sizers of different sizes.

DR. GIULIO RIZZOLI (Italy): I object to this comparison between pericardial and porcine prostheses, because we know that a pericardial prosthesis opens much more regularly and much more than any porcine

prosthesis. So the opening and the gradient is dependent upon the flow. Also, a patient in a resting condition has an advantage for the pericardial bioprosthesis over the porcine bioprosthesis.

DR. EICHINGER: Because of this, we are just making follow up six months postoperatively where we investigate all patients during exercise. We have an exercise protocol where we can really alter the flow which has to pass through the valve, and I think this will provide us with some important information.

DR. HORMOZ AZAR (USA): I think that patients don't come in just sizes 21 and 23. The rigidity of the frame also makes a difference, particularly for in-between patient sizes when you measure with a Hegar dilator. If the frame is rigid, it is not possible to implant the same diameter valve that you can when the valve has a slightly flexible frame. Do you have any comments?

DR. EICHINGER: I think this is a very important reason why we could not carry out oversizing in all patients, because in theory the Mosaic valve should always be implanted one size bigger. But that is not the reality - and this is exactly the point. A second point is whether the aortic root is very narrow, or is slightly dilated, as a dilated root enables much more upsizing than a very narrow root.