

Does the noise of mechanical heart valve prostheses affect quality of life as measured by the SF-36[®] questionnaire?☆

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Abstract

Objective: The closure clicks of mechanical heart valve prostheses' leaflets are quite often clearly audible. The study describes the effects of subjective valve sound perception on the patients' quality of life and analyses factors that might contribute to valve noise-related discomfort. **Methods:** We included 556 patients who received a mechanical valve prosthesis and participated in the study in our institution from 1994 to 1998. All compiled the standardised questionnaire Short-Form-36 Health Survey (SF-36[®]) and indicated their subjective disturbance grade pre- and postoperatively, then every 6 months up to 2 years. A series of factors was scanned for correlation with unpleasant noise perception. **Results:** Two years after the operation, only 5.8% classified their valve sounds as 'quite' or 'very much' disturbing. Age < 60 years and being female were statistically significant factors for persisting unease caused by valve sounds. Without one of these factors, severe disturbance chance was 1.5%. As expected, quality of life improved after surgery. Patients disturbed seriously by valve noise showed significantly lower mean life quality values on each SF-36[®] scale. **Conclusion:** Patients (94.2%) with mechanical heart valve replacement have no persistent complaints about the valve noise. The grade of annoyance by valve noise is paralleled by lower average quality of life. Age under 60 years or being female increases the probability of severe disturbance due to mechanical valve sounds. It remains unclear whether the disturbing noise is reason or consequence of lower quality of life.

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1. Introduction

In 1960, the first time mechanical heart valve prosthesis was implanted surgically. Today, prosthetic valve replacements are the second frequent cardiac surgical procedure with a yearly volume of about 16,000 operations in Germany and about 30,000 in the US-STS-database. About half of them are performed using mechanical valve prostheses. This kind of prostheses is durable [1] but thrombogenic, thus requiring anticoagulation. Valve developers, therefore, continue to modify prostheses material and shape [2,3], and a growing number of patients perform anticoagulation self-management [4,5], which has

led to improved quality of life. A still poorly addressed issue of mechanical valve prostheses is the noise they produce. This is perceived by many patients; many are happy to hear their heart constantly beating, but some dislike the noise. Valve noise might reduce quality of life. Often, the valve sound perception does not coincide with physically measured parameters of its intensity. Studies were performed using different valve models in aortic position in vitro [6] or vibration phonography [7]; others tried to quantify the acoustic differences between air and bone conduction and their effect on patient's perception of his own prosthetic valve sounds [8,9]. Further studies addressed the psychological and social aspects beside the physical properties of prosthetic sounds [10–14]. However, the instruments used to deal with quality of life were interviews asking for subjective feelings instead of standardised questionnaires designed for this purpose. The main aim of the present study was to explore to what extent the

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perception of prosthetic valve sound affects quality of life by applying the widely used tool Short-Form-36 Health Survey (SF-36®). Further, we looked for factors associated with being disturbed by valve noise.

2. Patients and methods

Quality of life and valve sound perception were secondary endpoints of the prospective controlled randomised early self-controlled anticoagulation trial (ESCAT [15]). The ESCAT trial was performed at the Heart Centre NRW from 1994 to 1998 and included 1200 consecutive patients who required mechanical heart valve prosthesis in the aortic, mitral or both positions. Patients had to be over 18 years and had to give their written informed consent to be enrolled in the study. The patients (or, in few cases, members of their families) have to be able to learn how to self-control their anticoagulation. Patients (90%) who were asked to participate in the study gave their consent and passed the self-control ability test. Exclusion criteria were contraindications for anticoagulation with Marcumar or Sintrom and a history of coagulation disorders.

At each examination (pre- and 6, 12, 18 and 24 months postoperatively), every patient was supposed to compile a standardised questionnaire and to report his personal grade of disturbance by the valve prostheses' noise. The follow-up examinations included history, clinical examination, laboratory parameters, electrocardiogram (ECG), Doppler echocardiography and medications. Within the planned 2-year follow-up period, 8.3% dropped out of the study, mainly due to intervention of their home doctors. The subset of 556 patients who had compiled the preoperative and the 2-year follow-up and lacked no or not more than one postoperative follow-up examination forms the population of the current study. Table 1 shows the patients' main demographic data and gives details on the implanted valves.

The ESCAT questionnaire that we used to determine quality of life was the SF-36® questionnaire [15]. We applied the approved German translation [16]. It consists of 36 standardised questions and condenses its results in eight scales. The eight scales describe: physical functioning (I), role functioning – physical (II), bodily pain (III), general health (IV), vitality (V), social functioning (VI), role functioning – emotional (VII) and mental health (VIII) (for details, see [15]). The noise-related question 'The heart valve noise disturbs me' could be completed by either checking 'not at all', 'somewhat', 'quite' or 'very much', and was asked separately from the SF-36® study in order to get precise information about the patients' noise perception quality.

2.1. Statistical analysis

We used SPSS Version 11.0.1 for the statistical analysis of our data. The evaluation of the SF-36® was performed with the standard evaluation program that is pertinent to the German SF-36® manual. The result after data classification and transformation is a value between 0 and 100 in all subscales, where a higher value indicates a better health condition. The results were presented as mean values (and 95% CI) for each scale. We avoided averaging the ordinal results of the noise-disturbance answer scale. Univariate comparisons to identify risk factors for low scale values were done with the χ^2 or Fishers exact tests, as appropriate. For pre–post comparisons, we used the *t*-test for paired samples.

3. Results

Within the 2-year study period, we got back 2758 compiled questionnaires, representing 4.96 questionnaires instead of the five that would mean a complete follow-up.

Table 1
Demographic data

Valve prostheses position	Aorta (<i>n</i> = 445)	Mitral (<i>n</i> = 76)	Both (<i>n</i> = 35)
Age (mean ± SD, range)	59.0 ± 10.5, 17–75	58.5 ± 10.6, 24–73	61.6 ± 8.5, 36–74
Male/female	330/115	37/39	16/19
Valve types			
CM	144 (32.4%)	24 (31.6%)	13 (37.1%)
MH	118 (26.5%)	16 (21.1%)	6 (17.1%)
SJM	183 (41.1%)	36 (47.4%)	16 (45.7%)
Valve diameters (mm:patients)			
<23:59		23:1	Aorta: <23:9
23:122		25:1	23:14
25:133		27:8	25:5
27:101		29:31	27:5
>28:30		31:35	29:2
			Mitral: 25:1
			27:4
			29:24
			31:6

SD, standard deviation; CM, carbomedics®; MH, medtronic hall®; SJM, St. Jude medical®.

Table 2
Results of the SF-36® scales (*n* = 556 patients)

Scale	Preoperatively mean/median	2 years median/mean
Physical functioning	52.1/50.0	75.6/80.0
Social role function	69.0/75.0	84.1/87.5
Physical role function	29.4/0	65.0/87.5
Emotional role function	49.1/33.3	71.3/100
Mental health	63.0/64.0	72.0/76.0
Vitality	44.9/45.0	59.5/60.0
Pain	64.1/62.0	79.7/84.0
General health	52.8/52.0	63.7/62.0
Noise is felt at	6 months	2 years
	(<i>n</i> = 556) patients	(<i>n</i> = 556) patients
Not disturbing (0)	254 (46.5%)	326 (58.6%)
Somewhat disturbing (1)	234 (42.9%)	200 (36.0%)
Quite disturbing (2)	39 (7.1%)	20 (3.6%)
Very much disturbing (3)	15 (2.7%)	10 (1.8%)
(2) or (3)	54 (9.8%)	30 (5.4%)

Table 2 lists the results of the SF-36® scales before and 2 years after the operation, as well as 6 and 24 months results of the noise-related question. Fig. 1A displays the mean values of all scales at any time point. The rate of patients who considered the valve prostheses' noise as annoying decreased continuously over the observed time points. After 2 years, valve noise remains 'very much disturbing' for only 1.8% and 'quite disturbing' for further 3.6%. Reduced quality of life on every scale can be found if average SF-36® scale values are plotted against increasing noise perception grade, as done in Fig. 1B: each scale value decreases with growing feeling of disturbance by valve noise.

Despite the small number of 30 patients who feel more than 'somewhat' disturbed by the valve noise, their scale score values after 2 years are significantly inferior than those of less annoyed patients (Fig. 2A). This is true for each of the eight SF-36® scales. To exclude the theoretically possible case that patients complaining more about the valve noise were preoperatively in worse conditions, we compared their preoperative quality of life scores and found more or less marked inferiority of their values, but no significant differences. Fig. 2B shows that even the patients who complain seriously about their valve noise after 2 years have a generally improved quality of life. They had no mean decrease of more than 5/100 points on any scale. The only scale where a (statistically not significant) deterioration of mean values can be seen is 'bodily pain', which can hardly be ascribed to the valve noise.

After looking for the various descriptive evaluations, we looked for possible risk factors for unease caused by valve noise. From the surgeons' view, more and larger valves might be suspected as a cause for more noise and, therefore, more complaints. The physician might speculate about the hearing that deteriorates with increasing age, and the psychologist might associate women as being the more sensitive sex. Analyses showed that valve size had no

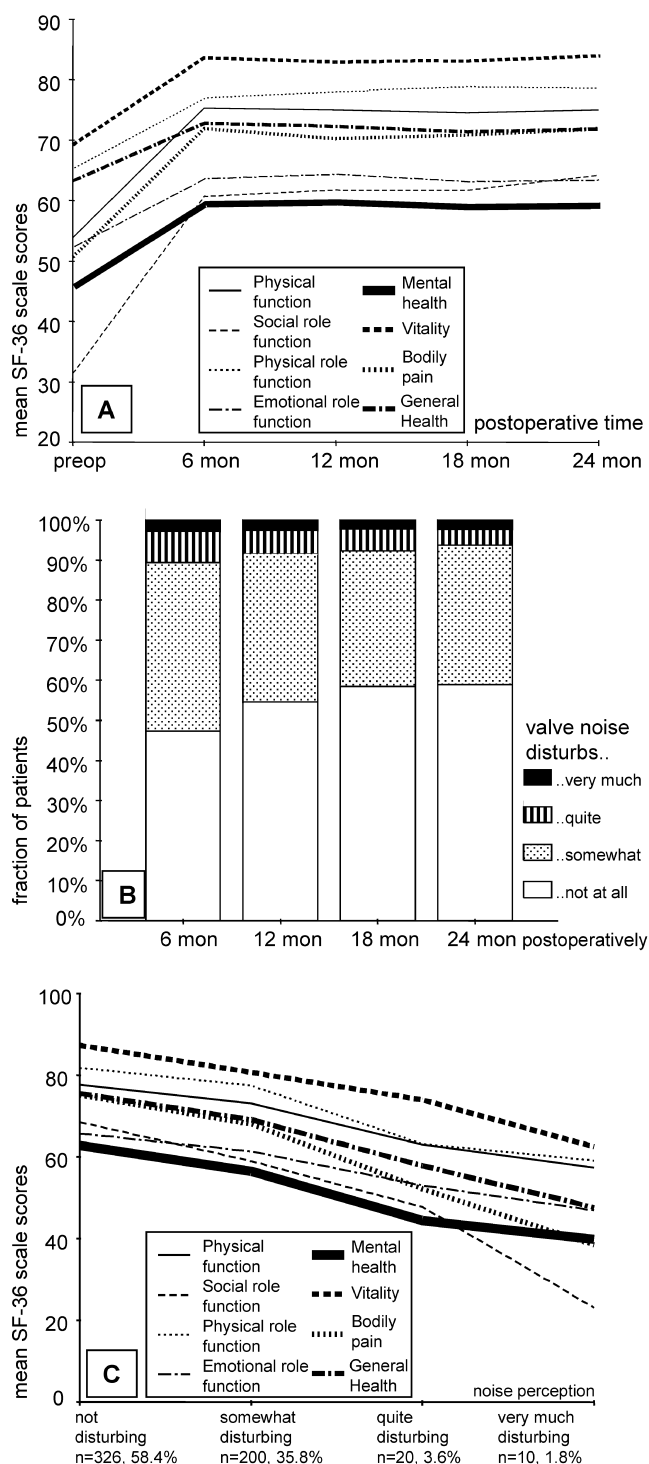


Fig. 1. SF-36 course and grades of noise-related disturbance. (A) Means of quality of life scores over time. The vertical axis shows the average scales' score values of the patients. A score of 100 is optimal, 0 is the lowest quality. A marked and persisting quality of life increase that involves each single scale is evident. (B) Shows the extent of habituation to the valve noise that can be observed mainly up to the 18th month. (C) This figure shows mean values for the different SF-36 scales after 2 years, related to the perception of valve noise. Even the minor graduations of noise perception coincide with decreasing mean values for quality of life. This is true for all eight scales.

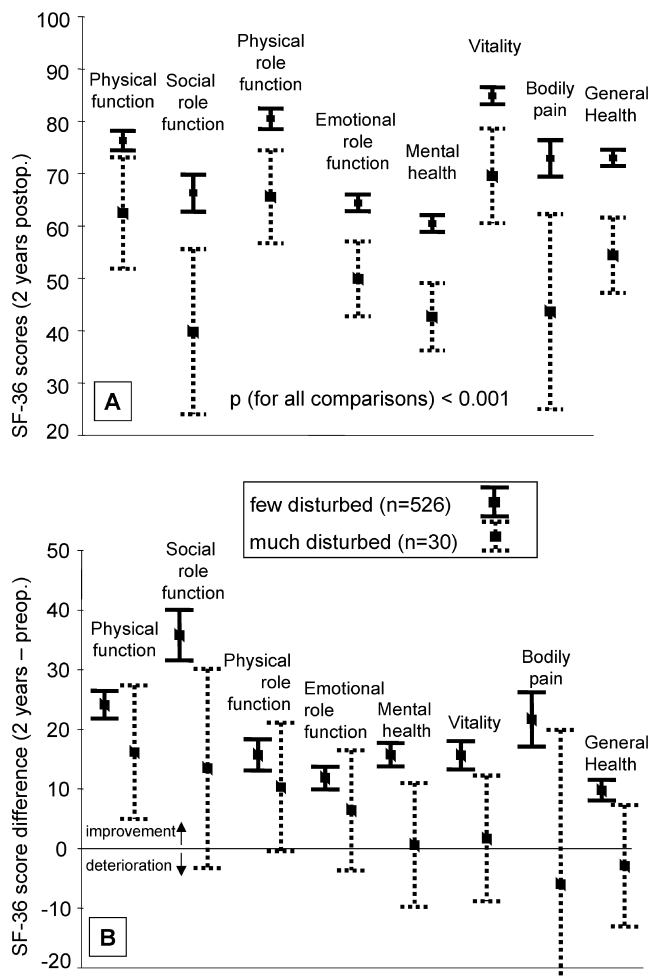


Fig. 2. Comparisons between ('quite' or 'very much') disturbed and non- (or 'somewhat') disturbed patients. (A) Two years after valve implantation, disturbed patients show significantly lower mean values for each scale than patients who consider themselves not seriously disturbed. (B) The changes (values 2 years postoperatively – preoperative values on an individual basis) in the different quality of life-scales are displayed here. Although the patients being disturbed by noise have lower average score improvements, in most of the scales, a mean improvement can still be seen. The deterioration in pain sensations can hardly be attributed to valve sounds.

significant influence at all. The valve (position (Fig. 3A), size, manufacturer) and even if one or two valves were implanted did not matter statistically significant. We tested other factors (weight, height, NYHA functional class, cardiac output, transvalvular peak gradient, systolic blood pressure, hemoglobine level) for association with being disturbed by valve noise: none of them showed any statistical significance (minimal *P*-value of 0.15).

Being over 60 years lowered the probability to be disturbed by valve noise (Fig. 3B): younger patients had a 2.7-fold higher chance to worry about that (Table 3). Being female increased the risk by the factor 3.8 when compared to being male (Fig. 3C). To show the main contrasts, old men's risk to be seriously disturbed by valve noise is 1.5%, 11.4 times lower than the risk of a young woman (Table 3). The combined analysis of age group and sex is shown in

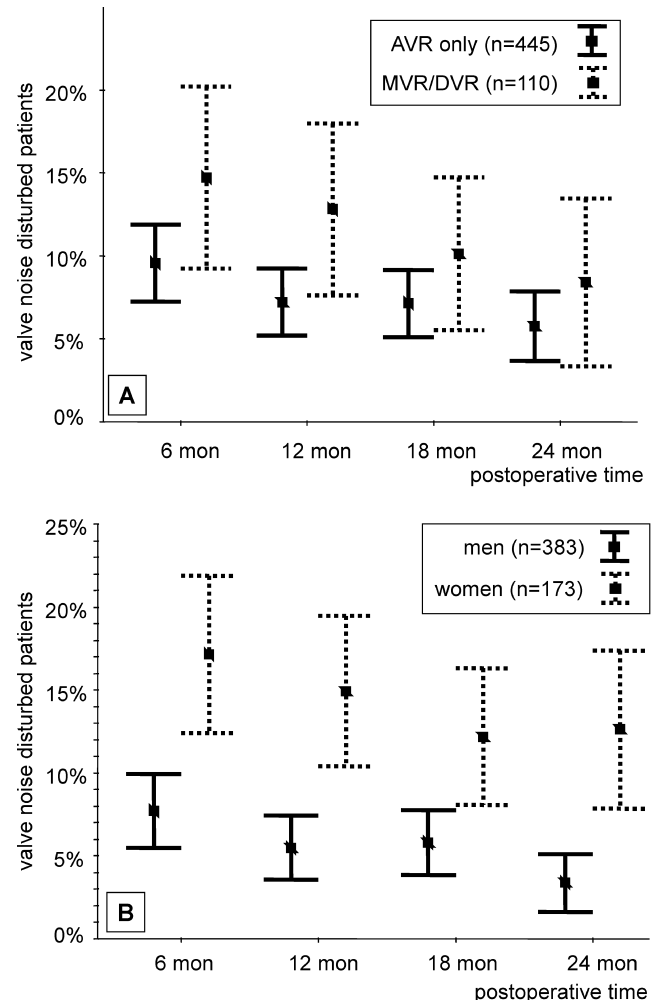


Fig. 3. The role of potential risk factors for unpleasant noise perception. The dashed lines show mean values and 95% confidence intervals of the percentage of disturbed patients (see legend for Fig. 2) and those who are not. (A) Valve position. Since the difference between double valve replacement patients (DVR) and mitral valve recipients (MVR) was small, we grouped both of them and compared their grade of disturbance with the patients after aortic valve replacement (AVR) only. The fraction of MVR/DVR patients who are disturbed by valve noise decreases over time, coming closer to the rate of patients with AVR. (B) Being female seems to be the most important factor for suffering from valve noise; although some habituation can be seen, over time women remain significantly more often disturbed than men.

Fig. 4: women between 30 and 60 years are the group that runs the highest risk for feeling disturbed by valve noise. Preoperative SF-36® scale values – if calculated as average values or after with dichotomisation with various cut off values – failed to show statistically independent (generalised linear models, multivariate analysis) predictors.

4. Discussion

Many studies dealt with the physical characters of prosthetic valvular sounds [6–9]. Others investigated their psychological aspects [10,11]. In contrast, the subjective

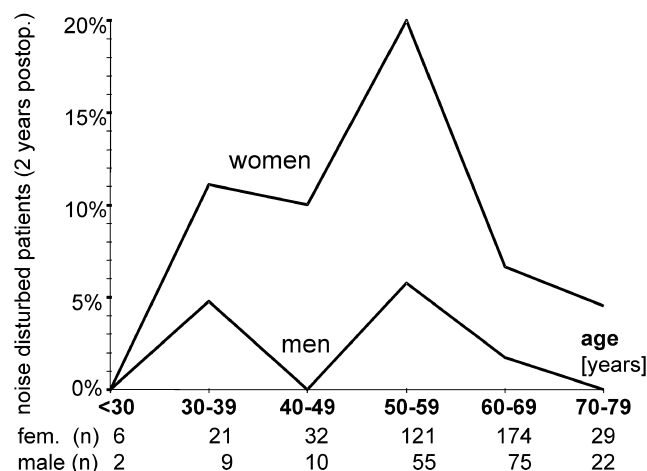


Fig. 4. The role of the main risk factors. Women between 30 and 60 years are the patient group most susceptible to being disturbed by valve noise.

perception of prosthetic valvular sounds has been addressed much more rarely. Limb [12] described in his work, that patients are annoyed that they and their partners are disturbed during sleep, that their ability to concentrate is restricted and that they feel socially torn apart.

In the present study, results of 556 heart valve prostheses recipients were examined as secondary endpoints from the ESCAT I study. They compiled a total of 2979 standardised questionnaires (SF-36®) and gave structured information about their grade of valve-related noise disturbance. Examination times were: before and 6, 12, 18 and 24 months after valve replacement.

The fact that 556 instead of 1200 ESCAT patients' data is used might be a limitation of the study. But coming into the hospital for the follow-up visits might not be a factor that has much to do with the patients' valve noise perception. If a bias might be considered, patients in worse conditions might feel more inclined to see their doctors – this might not change the observed

relation between quality of life and valve noise perception. Patients on worse conditions might be overrepresented, making results worse than they were if all patients had come.

The willingness to participate in the ESCAT study was present in 90% of the relevant patients; if this selection should introduce a bias in the attitude towards sound perception, the conclusions drawn from this study were still valid for 90% of the patients who received a mechanical heart valve prosthesis.

While 54.6% of the answer collective of our study showed no annoyance at all, 45.4% of answers showed various (mainly low) grades of annoyance. These values are close to the results of Moritz et al. [17] and Laurens et al. [13] who reported a value of 56% for any annoyance. Limb [12] found a value of 68% and Blome-Eberwein et al. [11] even indicated values reaching 86%; however, the latter referred to some extent to older valve types.

We observed adaptation to valvular sounds mainly within the first postoperative year (Fig. 1B), then the curve flattened. After 2 years, the percentage of patients who were not or only somewhat annoyed by the valvular sounds rose from 90.2 to 94.6%. Such adaptation is also described by Sezai et al. [10]. The adaptation to valve sounds after the sixth decade of life (Fig. 4) was shown to be related to the physically impaired hearing ability in the elderly. Old age difficulties in hearing especially concern the high frequencies, as the closing clicks of the valves [8,9].

The present study did not show any significant valve type, size or site related difference in valve noise perception. This coincides with the study of Laurens et al. [13], but stands in contrast to results of Sezai et al. [10] and Nygaard et al. [8] who found significant differences.

A strong relationship between prosthetic valve position, auditory perception and subjective estimate of life quality has been described. Patients who got an aortic prosthesis

Table 3
Factors associated with unpleasant noise perception

Factor	Patients	Disturbed by noise	Risk (%)	OR	P-value (χ^2 /Fisher)
(0) with MVR				1.2	0.6 (n.s.)
Yes	111	7	6.3		
No	445	23	5.2		
(1) Being female				3.8	<0.001
Yes	173	19	11.0		
No	383	11	2.9		
(2) Age < 60 years				2.7	0.006
Yes	256	21	8.2		
No	300	9	3		
Both of (1) and (2) (neither (1) nor (2))				11.4	<0.001
Yes	76	13	17.1		
No	203	3	1.5		
(1) or (2) or both				5.1	0.002
Yes	353	27	7.6		
No	203	3	1.5		

MVR, mitral valve replacement; OR, odds ratio.

were described to be less annoyed by the valve sounds than those who got mitral or combined valve surgery. Moritz et al. [14] explained that difference on the base of valve size, but recent measurements performed by Nygaard et al. [8] and Sezai et al. [10] do not approve that hypothesis.

It remains unclear whether valve noise creates worse quality of life or lower quality of life leads to more sensitive noise perception. A randomised study comparing quality of life in otherwise comparable patients with either noisy (mechanical prostheses) or noiseless (bioprostheses) devices would have to be restricted to patients around 70 years, but might help to clear the role of valve noise on quality of life.

5. Conclusion

Few patients (5.4%) suffer from noisy heart valve prostheses. This study showed female sex and age under 60 years to be relevant risk factors for persistently annoying valve noise perception. It remained unclear whether bothering noise perception was cause or consequence of lower quality of life. Both, further noise reduction and some kind of psychological preparation in the 'risk population' for the sound phenomenon, might help to mitigate this rarely unpleasant collateral effect of the generally very beneficial procedure.

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Appendix A. Conference discussion

Dr W. Mohl (Vienna, Austria): Do you think that this difference between men and women is due to the fact that there is a different resonance reservoir of the thorax, or could you quantitate this form of noise when it will be actually also correlated with the actual valve?

Dr Koertke: I think the difference is the resonance of the body. Another group in Athens, they compared these kinds of valves, and they showed there should be a difference between tilting disk and bileaflet. But the people feel different, and I think the body is very important, and the resonance of the body is very important. I think this kind of investigation shows us that we can offer the people a mechanical heart valve replacement and the sound is not significant.

Dr F. Casselman (Aalst, Belgium): Is there any particular reason why you did not include the ATS valve in your study, because this is the valve that has been reported to produce the least noise in the literature already?

Dr Koertke: Yes, the question is very interesting, but that had been done in a laboratory and not in this kind of investigation. ATS had been examined in Athens, I was just told, and they found that it could be a very, very comparative valve, but we only implanted very few valves in our hospital and that is the reason we didn't take that one in this kind of study.

Dr J. Hasenkam (Aarhus, Denmark): I would like to congratulate you very much for taking up this very important subject, which I think is very much ignored by most clinicians when we implant mechanical heart valves. Did you do any kind of objective measurements of these patients, for instance, measure their hearing ability?

Dr Koertke: No, we haven't done any of this kind of investigation.

Dr S. Al-Ruzzeh (London, United Kingdom): I have one question regarding the SF-36. It is a health quality-related questionnaire and there are eight domains measured by this questionnaire. Some of them couldn't really be related to noise, like physical domain. If somebody is physically limited, why do you think this is related to the noise of the valve? It could be more related to the mechanical efficiency of the valve.

Dr Koertke: I am not sure that I understand the question correctly. Could you repeat it?

Dr Al-Ruzzeh: What I am trying to say is SF-36 is a health-related

quality of life questionnaire. It measures eight domains. Some of them are emotional, which could be related to the noise of the valve, but others are physical. Why do you think physical limitation in a patient after valve replacement could be related to the noise of the valve?

Dr Koertke: Well, we had a second questionnaire, and we asked the people, how do you feel after valve replacement, can you sleep all right, what do you think the people around you feel about this kind of noise, does the noise make you very aggressive, do you hear the kind of noise? All these questions we had in a special questionnaire.

And then we got the results I showed you, and afterwards we gave them SF-36, and then we looked at what will happen if the people feel uncomfortable or feel the noise is valve-related, and then we ask them what will happen in general feelings of quality of life, and then we gave them SF-36. The results for feeling disturbed or not we didn't get from the SF-36. We got it from a special questionnaire we created for this kind of study.

Dr Al-Ruzzeh: Let me put the question another way. I agree with your method in actually studying the SF-36 in different types of valves, but I am

a bit reluctant to agree with you and studying it regarding, for example, the people who felt the noise of the valve in varying degrees, because I think it measures more domains than you expect to find any differences just by differences in emotional status being disturbed by a valve problem or a valve noise. I mean, some of the questions ask you, do you go out and visit friends? If I have a noise from the valve, why shouldn't I go out and visit friends? Because I have some experience with the SF-36. I think it measures the health in general rather than just emotional status or sleep deprivation.

Dr W. Mohl: This boils down to the question whether you quantitated this valve noise, no? Did you quantitate it over the time and was there a change in the quantitative noise that you could detect?

Dr Koertke: We quantitated the kind of noise if the patients felt very disturbed in the first six or 12 months postoperative and after that time they will accept this kind of noise, and 90% of all patients they have no problem with this kind of valve replacement, only 10% they felt a little bit disturbed. But of this 10, 8% of the patients will accept it in two years and only 2% of the patients have problems over time.