

Omniscience 인공 심장판막 삽입후 8년간 추적 관찰에 대한 결과 보고

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Results of Eight-Year Follow-Up of Omniscience Cardiac Prosthetic Valve

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ABSTRACT

Background and Objectives : This study was performed to assess the morbidity and mortality of 311 patients implanted with at least one Omniscience prosthetic valve between January 1992 and January 2000. **Subjects and Methods :** Following valve implantation all patients were followed up with routine interviews, physical examination and echocardiography. **Results :** The mean follow-up duration was 5.8 ± 0.9 (standard error, SE) years with a mean follow-up interval of 8.5 ± 0.7 (SE) months. The 311 patients received the following type (s) of valve : mitral, aortic, both or tricuspid valve, in 166 (47.9%), 99 (32.0%), 44 (19.5%) and 2 (0.6%) of cases, respectively. The cumulative follow up was 1143.4 patient-years (pt-yr). Death occurred in eight patients (0.7%/ pt-yr at linearized rate), and redo-operations were required in 27 patients (2.4%/pt-yr) due to valve failure. Actuarial freedom from all complication was $72.5\% \pm 8.2\%$ (SE). Freedom from pannus formation, paravalvular leak, or thromboembolism plus anticoagulant related bleeding were $83.1\% \pm 3.5\%$ (MVR/AVR $92.7\% \pm 4.7\%/73.4\% \pm 2.8\%$), $95.2\% \pm 2.1\%$ (MVR/AVR $96.8\% \pm 4.2\%/93.6\% \pm 3.2\%$), and $96.1\% \pm 2.5\%$ (MVR/AVR $95.6\% \pm 5.6\%/96.7\% \pm 4.7\%$) respectively. **Conclusion :** Our results with this prosthesis demonstrate relatively high incidences of valve related complication especially due to pannus formations and paravalvular leaks. We could reduce the incidences of mortality by earlier detection of complications, redo-operations and routine checks. (**Korean Circulation J 2002;32(7):588-595**)

KEY WORDS : Heart valve prosthesis ; Prosthesis failure ; Follow-up studies.

서 론

Omniscience Lillehei - Kaster Va-

: 2001 2 5

: 2002 3 25

: 2002 5 31

: , 301 - 725

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Ive¹⁾ 3 Omniscie-
nce Omnicarbon valve
1978 8 Ohio Kettering Medical Cen-
ter
. 1984 titanium
housing carbon disc low - profile, mon-
oleaflet curved radio - opaque .

. Flow channel 2400 mL/m³/min
 Omniscience 2-4) 가

대상 및 방법

대 상
 1992 1 2000 1
 311 /
 174/137 (Mitral valve replacement, MVR) 166(47.9%) ,
 (Aortic valve replacement, AVR) 99 (32.0%),
 44 (19.5%)
 2 (0.6%)
 43.4 ± 14.2 years(SD) . New York
 Heart Association(NYHA) classes III or IV가 79%
 (Table 1).

수술방법

3 mg/
 kg
 가
 가
 vent cannular

1 mL/kg
 36.6 가
 가
주적관찰 및 항응고제 투여
 2
 1 , 6 1 , 8.5
 ± 0.9(SE)
 wafarin 2 pro-
 thrombin time INR(International Normalized Ra-
 tio) system

통계방법

Society for Thoracic Surgeon
 5) mean ± standard error(SE)
 standard deviation(SD) plotting
 life - table method , Anderson
 son 6)7) un-
 paired t - test Mann - Whitney test

결 과

Table 1. Demographic and clinical characteristics

Characteristic	MVR (n=166)	AVR (n=99)
Sex		
Male	92	55
Female	74	44
Age (mean, year)	42.4 ± 7.6	48.4 ± 12.5
NYHA class (mean)	3.2 ± 0.7	3.5 ± 0.5
Valve size (mm)	23.6 ± 3.1	27.6 ± 3.4
Rheumatic	125 (75.3%)	74 (75.2%)
Previous valve prosthesis failure	12 (7.2%)	8 (8.0%)

MVR : mitral valve replacement, AVR : aortic valve replacement, NYHA : New York heart association

Rheumatic 75.2%,
 10.3% 가
 가
 54 (17%) CABG 5 (1.6%)

사망 및 재수술 환자군

8 mortality 2.5%, linearized rate
 0.7%/pt - yr . Candida 1 ,
 2 , 2 ,

pannus leak 1 , 1 3 2 redo MVR AVR
 . Omniscience 2 1
 27 (2.71%±0.5%/pt - yr) MVR/AVR
 actuarial free rate 90.8%±2.7%/82.6%±
 2.5% (Fig. 4). pannus growth
 15 , paravalvular leak
 11 , 4 ,
 2 , 1 (Table 2).

합병증 환자군

8 actuarial event free rate
 72.5%±2.5% MVR/AVR 76.2%±7.2%/
 69.7%±2.6% (Fig. 1).

혈전증 및 항응고제 관련된 출혈

Linearized rate MVR/AVR 1.9%±0.2%/pt - yr,
 1.4%±0.3%/pt - yr
 (4) AVR (3)
 18 MVR

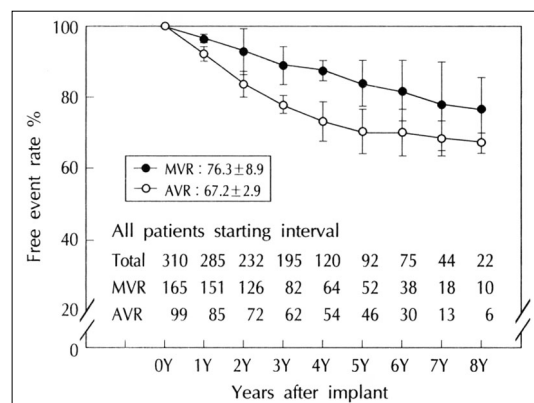


Fig. 1. Actuarial freedom from all complications. MVR : mitral valve replacement, AVR : aortic valve replacement.

Table 2. Causes of redo-operation for Omniscience valve failure

	MVR (n=166)	AVR (n=99)	Total
Paravalvular leak	6	5	11
Pannus	7	8	15
Valve thrombus	4		4
Endocarditis		1	1
Hemolysis	1	1	2

MVR : mitral valve replacement, AVR : aortic valve replacement

redo MVR AVR
 INR 3.5
 (Table 4).

심내막염

MVR 3 , AVR 1 actuarial free rate
 98.9%±3.2%, 99.0%±1.9%

용혈

hemoysis paraval-
 vular leak 4 3
 가 . Linearized rate MVR 0.3%

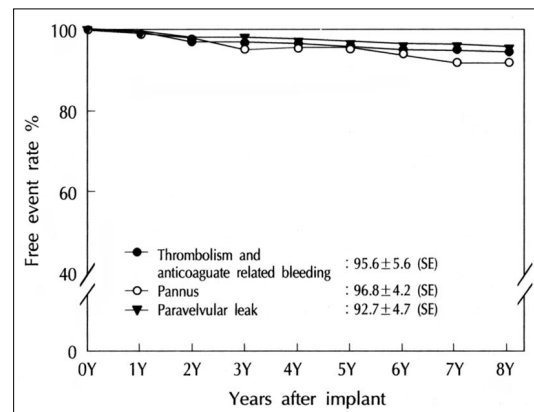


Fig. 2. Actuarial freedom from complication after MVR. MVR : mitral valve replacement, SE : standard error.

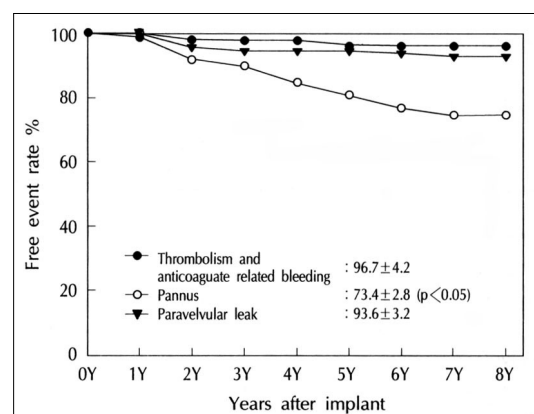


Fig. 3. Actuarial freedom from complications after AVR. p value represents comparing pannus with other two complications. AVR : aortic valve replacement.

$\pm 0.1\%/pt - yr$, AVR $0.5\% \pm 0.2\%/pt - yr$.

. Actuarial free rate 96.8%
 $\pm 4.2\%$, $93.6\% \pm 3.2\%$. AVR 4 12
 trivial 2 MVR
 4 .

Paravalvular leak

MVR 9 3 AVR 6 5

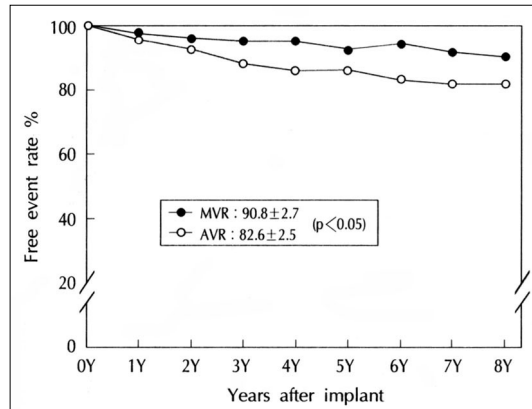


Fig. 4. Actuarial freedom from redo-operation. MVR : mitral valve replacement, AVR : aortic valve replacement.

가 .
 (Fig. 2, 3).

Pannus formation

가
 MVR 12
 $1.7\% \pm 0.4\%/pt - yr$, actuarial free rate $92.7 \pm 4.7\%$,
 AVR $6.1\% \pm 0.9\%/pt - yr$, $73.4\% \pm 2.8\%$
 $p < 0.05$
 (Fig. 2, 3). MVR 6 , AVR 8
 1
 (p<0.05)

Table 3. Echocardiographic findings

Finding	Preop	Postop	Eight-year
Ejection Fraction (mean)%	58.0 ± 13.7	56.24 ± 14.2	58.3 ± 13.5
Valve angle (°)			
Aortic valve pressure gradient (mmHg)			
of AVR patients			
Peak	68.9 ± 34.3	26.7 ± 5.6	69.5 ± 3.2*
Mean	48.0 ± 12.6	16.2 ± 3.2	42.1 ± 15.5
Mitral valve pressure gradient (mmHg)			
of MVR patients			
Mean	10.4 ± 4.6	3.4 ± 2.6	32.2 ± 9.6
Mitral valve area (cm ²) of MVR patient			4.1 ± 3.2
2D planimetry	1.0 ± 0.7	1.7 ± 0.5	
Pressure half time	1.1 ± 0.3	1.8 ± 0.6	1.5 ± 0.4

* : for fifty patients 4 - 8 years after operation, AS : aortic stenosis, AR : aortic regurgitation, MS : mitral stenosis, MR : mitral regurgitation

Table 4. Incidence and linearized rate of complications and consequences

Complications	MVR (n=166)			AVR (n=99)		
	Events	Linearized rate*	Actuarial freedom†	Events	Linearized rate*	Actuarial freedom†
Thromboembolism and anticoagulant bleeding	14	1.9 ± 0.2	95.6 ± 5.6	6	1.4 ± 0.3	96.7 ± 4.2
Prosthetic endocarditis	3	0.4 ± 0.1	98.9 ± 3.2	1	0.2 ± 0.0	99.0 ± 1.9
Pannus formation	12	1.7 ± 0.4	92.7 ± 4.7	26	6.1 ± 0.9	73.4 ± 2.8
Paravalvular leak	9	1.3 ± 0.3	96.8 ± 4.2	6	1.4 ± 0.5	93.6 ± 3.2
Hemolysis	2	0.3 ± 0.1	98.9 ± 3.4	2	0.5 ± 0.2	91.5 ± 5.6
Total	40	5.6 ± 0.3	76.2 ± 7.2	41	9.6 ± 0.5	69.7 ± 2.6
Redo-operation	15	2.1 ± 0.6	90.8 ± 2.7	12	3.8 ± 0.8	82.6 ± 2.5

* : %/pt-yr ± SE, † : % ± SE, MVR : mitral valve replacement, AVR : aortic valve replacement

Table 5. Publications reporting long-term results of valve replacement²¹⁻²³⁾

Follow-up time							Complication : linearized rate (%/pt-yr) Actuarial freedom from event (%±SE)						
Reference	Total	Max	Mean	Total patients	Age average	Prosthesis	TE+ARH	HA	Endocarditis	Paravalvular leak	Pannus	Late death	Redo-operation
AVR													
Akins, 1996 (9)	765	10.3	4.3	177	57	Medtronic hall	3.0 ND	0 100	0.6 96.2±2	0 100	0.1 99.1±1	2.5 72±6	ND
Arom, 1989 (22)	2380	10	3.8	698	64	St. Jude	ND	0	ND	ND	0	3.6	ND
Fernandez, 1994 (23)	1676	10	3.8	698	58	St. Jude	2.1	ND	0.6	0.4	0.1	ND	ND
Teijeira, 1997 (21)	680	13	8.3	85	58	Omniscience	2.2 79±5	0 100	0.4 96±2	0.4 95±3	0.1 99±1	2.8 71±6	ND
Kim, 2000 (present study)	424	8	5.9	99	48	Omniscience	1.4 96±4	0.5 91±5	0.2 99±2	1.4 93±3	6.1 73±3	1.3 94±7	3.8 83±2
MVR													
Akins, 1996 (9)	481	10.3	4.6	106	62	Medtronic hall	4.0 ND	0 100	1.0 88±5	2.1 82±6	0 100	4.4 63±7	ND
Arom, 1989 (22)	1471	10	3.8	464	60	St. Jude	ND	0	ND	ND	0.1	5.6	ND
Fernandez, 1994 (23)	1305	10	2.9	490	58	St. Jude	4.7	ND	0.5	1.1	0.1	ND	ND
Teijeira, 1997 (21)	716	12.5	7.7	103	56	Omniscience	2.1 83±5	0 100	0.1 99±1	0.3 98±2	0.3 97±3	3.2 67±5	ND
Kim, 2000 (present study)	719	8	4.9	166	42	Omniscience	1.9 95±5	0.3 99±3	0.4 99±3	1.3 97±4	1.7 92±5	0.4 99±5	2.1 91±3
Our follow-up duration was eight years. ND : no data from authors, TE : thromboembolism (including valve thrombosis), ARH : anticoagulant related hemorrhage													

Our follow-up duration was eight years. ND : no data from authors, TE : thromboembolism (including valve thrombosis), ARH : anticoagulant related hemorrhage

3 Omniscience (Medical Inc., InverGrove Heights, Minn.)
 . Pannus (43.4
 가 2 ± 14.2) Rheumatic 가
 가 (MVR/AVR 75.3%/75.2%),
 Omniscience
 가 7.2%, 8.0%

심조음파 소견

가 MVR/AVR 49/4 AVR
 가 5 , 가
 4
 8 50 valve angle 1 , 가 5
 fluoroscope 69.5±
 3.2° 71±5.2°
 parasternal long axis apical two - (0.7%/pt - yr) 1992 Akalin ²⁰⁾
 chamber view 가 . Pannus 2.0%, 1998 Teijeria 2.8%
 AVR 8 가 3 4
 pressure gradient가 가 redo - operation
 50 mmHg
 12 redo - operation
 가 linearized rate 2.7%/
 . MVR pannus AVR pt - yr
 mean pr-
 essure gradient가 5 mmHg pannus가 15 55% paravalv-
 pannus 1.5 ular leak 11 (41%), valve thrombus가 4 (14%),
 cm² 가 ak 1 , paravalvular le-
 (Table 3). 2
 6

고 찰

MVR/AVR(1.9%±0.2/1.4%±0.3%/pt - yr)
 1960 ¹⁴⁾¹⁵⁾
 paravalvular leak
 actuarial free rate 98.9%±3.2%/99.0%
 ±1.9%, 98.9%±3.4%/91.5%±5.6%
 가
⁸⁾ 1996 Akins ⁹⁾ Om-
 niscience 9 가
 . Omnisci- paravalvular leak pannus
 ence 1978 ¹¹⁾ nus Evangelista ¹⁶⁾ . Pan-
 가 1981 prosthetic disc mul-
^{12 - 14)}
 1992 tiple dense echo

follow-up

10

8

가

NYHA functional class 8

actuarial survival rate NYHA Class , ,

$91\% \pm 3.1\%(\text{SE})$, $83\% \pm 5.2\%(\text{SE})$,

$62\% \pm 4.5\%(\text{SE})$ NYHA Class

가

가

.

요약

배경 및 목적 :
Omniscience 8

방 법 :
1992 1 2000 1 8
Omniscience 311

결 과 :
follow - up 5.8 ± 0.9
8.5 ± 0.7
43.4 ± 14.2 166 (47.9%)
MVR, 99 (32.0%) AVR , 44 (19.5%)
DVR 2 (0.6%) TVR
1143.4 patient - years (pt - yr), 8
linearized rate 0.7%/pt - yr,
27 (2.4%/
pt - yr) actuarial freedom

rate 72.5% ± 8.2% pannus 83.1% ± 3.5% (MVR/AVR 92.7% ± 4.7%/73.4% ± 2.8%), paravalvular leak 95.2% ± 2.1% (MVR/AVR 96.8% ± 4.2%/93.6% ± 3.2%), thromboembolism 96.1% ± 2.5% (MVR/AVR 95.6% ± 5.6%/96.7% ± 4.7%) .

결 론 :

Omniscience pannus
paravalvular leak

중심 단어 : Omniscience ; Pannus ;
Paravalvular leak ; .

REFERENCES

- 1) Mikhail AA, Ellis R, Johnson S. Eighteen-year evolution from the lillehei-kaster valve to the omni design. *Ann Thorac Surg* 1989;48 (Suppl):S61-4.
- 2) Bjork VO. The optimal opening angle of the bjork-shilley tilting disc valve prosthesis. *Scand J Thorac Cardiovasc Surg* 1981;15:223-7.
- 3) Esper E, Ferdinand FD, Aronson S, Karp RB. Prosthetic mitral valve replacement: late complications after native valve preservation. *Ann Thorac Surg* 1997;63:541-3.
- 4) Prabhakar G, Kumar N, Hatle L, al-Halees Z, Duran CM. Accelerated failure of bioprosthesis by entrapment in chordal-sparing mitral valve replacement. *J Thorac Cardiovasc Surg* 1994;108:185-7.
- 5) Edmunds LH, Clark RE, Cohn LH, Miller DC, Weisel RD. Guideline for reporting morbidity and mortality after cardiac valvular operations. *Ann Thorac Surg* 1988;46:257-9.
- 6) Grunkemeier GL, Starr A. Actuarial analysis of surgical results: rationale and method. *Ann Thorac Surg* 1977;24:404-8.
- 7) Anderson RP, Bonchek LI, Grunkemeier GL, Lambert LE, Starr A. The analysis and presentation of surgical results by actuarial methods. *J Surg Res* 1974;16:224-30.
- 8) Morgan RJ, Davis JT, Fraker TD. Current status of valve prosthesis. *Surg Clin North Am* 1985;65:699-720.
- 9) Akins CW. Results with mechanical cardiac valvular prostheses. *Ann Thorac Surg* 1995;60:1836-44.
- 10) Minardi G, di Segni M, Boccardi L, Ferrari O, Giovannini E. Doppler echocardiography in assessing mechanical and biologic heart valve prosthesis. *G Ital Cardiol* 1988;18:121-34.
- 11) de Wall RA, Pelletier LC, Panebianco A, Hicks G, Schuster B, Bonan R, Martineau JP, Yip L. Five year clinical experience with the omniscience cardiac valve. *Ann Thorac Surg* 1984;38:275-80.
- 12) Fananapazir L, Clarke DB, Dark JF, Lawson RA, Mousalli H. Results of replacement with the omniscience prosthesis. *J Thorac Cardiovasc Surg* 1983;86:621-5.
- 13) Rabago G, Martinell J, Fraile J, Andrade IG, Montenegro R. Results and complication with the omniscience prosthesis. *J Thorac Cardiovasc Surg* 1984;87:136-40.
- 14) Cortina JM, Martinell J, Artiz V, Fraile J, Rabago G. Comparative clinical results with omniscience (STM1), medtronic-hall, and bjork-shilley convexo-concave (70 degrees) prosthesis in mitral valve replacement. *J Thorac Cardiovasc Surg* 1986;91:174-83.
- 15) Damle A, Coles J, Teijeira J, Pelletier C, Callaghan J. A six-year study of the omniscience valve in four Canadian centers. *Ann Thorac Surg* 1987;43:513-21.
- 16) Evangelista Masip A, Bruguera Cortada J, Serrat Serradell R, Robles Castro A. Echocardiographic findings in pannus ingrowth on an omniscience mitral prosthesis. *Clin Cardiol* 1987;10:611-3.
- 17) Carrier M, Martineau JP, Bonan R, Pelletier LC. Clinical and hemodynamic assessment of the omniscience prosthetic heart valve. *J Thorac Cardiovasc Surg* 1987;93:300-7.
- 18) Cordoba M, Almeida P, Martinez P, Maravi C, Ramirez JA, Rabago G. Invasive assessment of mitral valve prosthesis. In: Rabago G, Cooley DA, editor. *Heart valve replacement and future trends in cardiac surgery*. 1st ed. New York: Futura; 1987. p.375-89.
- 19) Misawa Y, Hasegawa T, Kato M, Ide H. Clinical experience with omniscience and omnicarbon prosthetic heart valves. *Nippon Kyobu Geka Gakkai Zasshi* 1991;39:885-90.
- 20) Akalin H, Corapcioglu ET, Ozyurda U, Ucanok K, Uysalel A, Kaya B, Eren NT, Erol C. Clinical evaluation of the Omniscience cardiac valve prosthesis. *J Thorac Cardiovasc Surg* 1992;103:259-66.
- 21) Teijeira FJ. Long-term experience with the omniscience cardiac valve. *J Heart Valve Dis* 1998;7:540-7.
- 22) Arom KV, Nicoloff DM, Kersten TE, Northrup WF 3rd, Lindsay WG, Emery RW. Ten years' experience with the st. jude medical valve prosthesis. *Ann Thorac Surg* 1989;47:831-7.
- 23) Fernandez J, Laub GW, Adkins MS, Anderson WA, Chen C, Bailey BN, Nealon LM, McGrath LB. Early and late-phase events after valve replacement with the st. jude medical prosthesis in 1200 patients. *J Thorac Cardiovasc Surg* 1994;107:394-407.