

# A MECHANICAL OPTION TO TISSUE VALVE REPLACEMENT?

*Clinical Update  
Number Fourteen*



## Substantial reduction of blood destruction and morbid events could lead to lowered INR for recipients of the On-X® Prosthetic Heart Valve.

Many surgeons/patients today are choosing tissue prostheses when valve replacement is necessary primarily due to hemorrhagic complications associated with anticoagulants for mechanical valve recipients. In 1998, the American College of Cardiology/American Heart Association Task Force recommended bioprostheses for aortic valve patients older than 65 years and for mitral valve patients older than 70 years.<sup>1</sup> In 2002, the Euro Heart Survey of the European Society of Cardiology found these age limits at 70 and 75 years respectively which is consistent with other current recommendations.<sup>2,3</sup>

### A need for complete understanding of alternatives

Through wider use of the internet, patients are self-educating and are requesting tissue products because of fear of anticoagulants. Patients who have not experienced cardiopulmonary bypass and sternotomy are naively accepting the idea that reoperation for tissue valve replacement will not increase their risk and discomfort a decade later. Also, most patients are unaware that a substantial portion of tissue valve recipients will require anticoagulants anyway.

### Tissue prosthetic implant must be re-examined

Current comparative studies and older randomized studies show no statistical difference in morbid event rates between tissue and mechanical valves.<sup>4-11</sup> Reoperation hazard for stented tissue valve deterioration offsets hemorrhagic complications for mechanical valves (Table 1).<sup>4-11</sup> Mortality rates for patients with tissue prostheses are worse than those of older generation mechanical valves.<sup>4-11</sup>

Table 1. Summary of morbid event rates for bioprostheses and mechanical valves.<sup>9</sup>

Events	Bioprostheses % per pt.yr.	Mechanical % per pt.yr.
Thromboembolism	0.6-3.9	0.6-3.5
Hemorrhage	0.1-1.9	0.6-4.0
Reoperation	3.4	0.7
Mortality	1.4	0.7

### Structural deterioration of tissue valves is hazardous to patients

Tissue valve failure dramatically increases after 8 years for porcine valves and after 10 years for pericardial valves.<sup>5</sup> Life spans in Western culture for both men and women have substantially increased in the last 20 years.<sup>10</sup> Therefore, if a patient who is 65-70 years old receives a tissue valve, he/she will likely be living and require reoperation at 70-80 years old with a dramatic increase in operative morbidity and mortality risk (Table 2).

Table 2. Reoperative mortality increases with patient age<sup>11,12</sup>

Reoperative Mortality		
60-70 years	> 70 years	> 80 years
11.5%	17.3%	32%

Reoperation in the eighth decade of life leads to high rates of morbidity and mortality. Kirsch, et al., state, ". . . , these findings must be taken into account for the . . . choice of heart valve prosthesis at the initial operation in younger patients."<sup>12</sup> As many as 50% of mitral valve replacement patients with bioprostheses and 30% of aortic valve replacements receive long-term warfarin therapy.<sup>10</sup>

Table 3. Comparison of On-X valve and tissue valve morbid event rates<sup>17-20</sup>

Valve Mean Follow-up	On-X <sup>17</sup> Aortic 4 years	On-X <sup>17</sup> Mitral 4 years	CEP <sup>18</sup> Aortic 5 years	CEP <sup>19</sup> Mitral 8 years	Freestyle <sup>20</sup> 2 years
Thromboembolism	1.0	1.0	1.4	1.1**	2.5*
Hemorrhage	0.6	0.5	0.1*	1.1**	1.4*
Thrombosis	0	0	0	0	0
Structural Failure	0	0	0.3*	1.6*	0
Total	1.6	1.5	1.8	3.8	3.9

\*Calculated at MCRI from available information \*\*Major events only

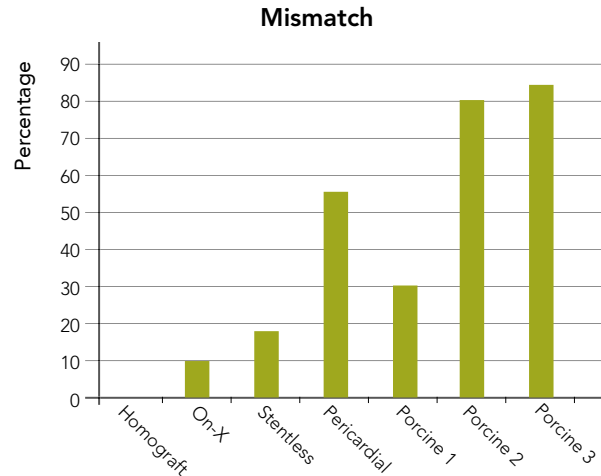
## The On-X valve reduces morbid event rates and reoperation

Clinical trials have proven that use of the On-X® Prosthetic Heart Valve has cut morbid event rates by 50% or more.<sup>13-17</sup> The On-X valve provides morbid event rates that rival those of tissue valves and eliminates unnecessary reoperations due to structural failure (Table 3).<sup>17-20</sup> This remarkable performance has led to an “aspirin only” trial unique to the On-X valve that is ongoing in Germany at 18 months. Other alternatives to standard anticoagulation for the On-X valve are also being examined in studies.

## Stentless valves are not a hemodynamic advantage to the On-X valve

The advent of stentless valves has produced hemodynamics that are more acceptable than those seen with stented products. The On-X valve is the first prosthesis on the market, tissue or mechanical, with mean gradients less than 10mmHg in every size.<sup>17</sup> Figure 1 shows that hemodynamics for the On-X valve are better and that it provides less mismatch than all commercially prepared tissue valves except for homografts.<sup>21</sup>

Figure 1. % of patients mismatched for different prosthetic valves



Risk of reoperation from structural failure is a danger to patients who receive tissue valve implants. The On-X® Prosthetic Heart Valve eliminates this risk and provides better hemodynamics and the near natural morbid event rates of tissue prostheses.

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## On-X aortic and mitral valves are FDA approved.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. INDICATIONS FOR USE: The On-X® Prosthetic Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic and mitral positions. CONTRAINDICATIONS: The On-X Prosthetic Heart Valve is contraindicated for patients unable to tolerate anticoagulation therapy. WARNINGS AND PRECAUTIONS: 1. FOR SINGLE USE ONLY. 2. DO NOT use the On-X Prosthetic Heart Valve if: the prosthesis has been dropped, damaged, or mishandled in any way; the tamper evident seal is broken; the serial number tag does not match the container label; or the expiration date has elapsed. 3. DO NOT re-sterilize any On-X Prosthetic Heart Valve once it is removed from its plastic container. 4. DO NOT re-sterilize more than 3 times. 5. DO NOT re-sterilize with any method other than steam sterilization, with the identified re-sterilization parameters. Note: Gamma radiation is known to damage the sewing ring. 6. DO NOT pass a catheter, surgical instrument, or transvenous pacing lead through the prosthesis as this may cause valvular insufficiency, leaflet damage, leaflet dislodgment, and/or catheter/instrument/lead entrapment. 7. Handle the prosthesis with only MCRI® On-X Prosthetic Heart Valve Instruments. Only MCRI On-X Prosthetic Heart Valve Sizers should be used during the selection of the valve size; other sizers may result in improper valve selection. 8. Avoid damaging the prosthesis through the application of excessive force to the valve orifice or leaflets. 9. Avoid contacting the carbon surfaces of the valve with gloved fingers or any metallic or abrasive instruments as they may cause damage to the valve surface not seen with the unaided eye that may lead to accelerated valve structural dysfunction, leaflet escape, or serve as a nidus for thrombus formation. POTENTIAL ADVERSE EVENTS: Adverse events potentially associated with the use of prosthetic heart valves (in alphabetical order) include, but are not limited to: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, myocardial infarction, prosthesis leaflet entrapment (impingement), prosthesis non-structural dysfunction, prosthesis pannus, prosthesis perivalvular leak, prosthesis regurgitation, prosthesis structural dysfunction, prosthesis thrombosis, thromboembolism and stroke. It is possible that these complications could lead to: reoperation, explantation, permanent disability and death.

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