SONOLUMINESCENCE ON MECHANICAL HEART VALVES AND ITS APPLICATION TO THE EVALUATION OF CAVITATION SEVERITY

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Abstract: Cavitation occurs on mechanical heart valves (MHVs), and it could cause damage to MHV materials and blood cells. Several *in vitro* test methods of cavitation have been developed so far. Imaging methods of cavitation bubbles using a stroboscope or a high-speed camera can easily capture bubble images. These methods, however, cannot capture the bubble implosion, which actually induces harmful effects. Implosion of cavitation bubbles causes various effects. One of these effects is sonoluminescence. Faint light emission from cavitation on MHVs was observed to evaluate the cavitation severity in this study. First, submerging the MHV specimen in deionized water, photographic images were captured using a stroboscope, and the occurrence of cavitation was confirmed on a 20-mm Björk-Shiley and the FDA Round Robin 27-mm MHVs (Medtronic Hall, Edwards Duromedics and St Jude Medical). Second, a photomultiplier tube was applied to capture the violent cavity collapse by observing sonoluminescence. Then, diluted blood was prepared and sonoluminescence was observed in *in vitro* blood testing. Comparing the photographic images with the faint light observations, the behavior of the bubble implosion around MHVs was successfully observed based on sonoluminescence.

Introduction

Mechanical heart valves (MHVs) are used as prostheses for the patients with irreversible heart valve failure. The replacement of the diseased heart valves by these prostheses has been an established medical treatment for more than 40 years. The introduction of pyrolytic carbon in the 1970s into MHVs provided the excellent biocompatibility and durability [1]. In the late 1980s, however, it was reported that some MHVs were broken in *in vivo* application [2] and in *in vitro* tests [3,4]. The investigation of damage concluded that these troubles were caused by cavitation. Then the cavitation has been drawing attention of the researchers, the manufacturers and the regulating agencies of MHVs. The brief summary of the MHV cavitation research was given in reference [5].

Since the early 1990s, a simple and reliable *in vitro* test method of the cavitation has been sought to assess the cavitation potential of MHVs. The U.S. Food and Drug Administration (FDA) proposed its protocol and conducted the interlaboratory comparison of the test results [6], and some researchers also tried their own evaluation methods [4,7,8]. These methods could not lead to the consistent conclusion about the cavitation potential of MHVs, so that there is still no standard of the *in vitro* cavitation test on MHVs. Damage due to cavitation occurs at the instant of the collapse of the cavitation bubbles. Therefore, the bubble implosion must be observed to analyze the cavitation damage. Because most of the previous methods were based on the visual detection of the cavitation bubbles using stroboscopes or high-speed cameras, these methods couldn't capture the cavity collapse with their insufficient spatial and temporal resolutions.

Some researchers applied another method to detect the cavitation bubble collapse. High frequency oscillation (HFO) caused by the bubble implosion was recorded with hydrophones [9,10] and used as a proof of cavitation, but the FDA indicated that the structure of the MHV also induces this kind of oscillation in the ultrasound region and concluded that HFO cannot be a reliable proof of the cavity collapse [11]. Still, some new method to specifically detect the bubble implosion has to be developed to evaluate the cavitation potential of MHVs. To investigate the cavitation on MHVs, it is important to obtain the spatiotemporal information about the collapse of the cavitation bubbles.

The implosion of the cavitation bubbles induces various effects [12]. One of these effects is sonoluminescence. At the bubble implosion, the inside of the bubble is exposed to extremely high temperature and high pressure. High temperature produces plasma (the ionized gas) and excited free radicals inside the bubble. Plasma emits light because of bremsstrahlung, and the excited free radicals emit light when they return to their ground states [13]. For example, the excited OH radical emits UV light of 310 nm in wavelength. In this way, the cavitation bubbles emit the faint light at their implosion, and this phenomenon is called sonoluminescence. Sonoluminescence caused by ultrasound was observed to evaluate the free radical formation for medical devices [14,15]. Light emission due to cavitation has been reported also in the hydrodynamic cavitation fields, such as in the flow through the Venturi tube [16]. Cavitation

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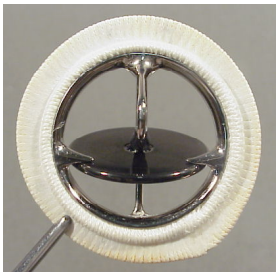
actually occurs around the MHVs, and thus sonoluminescence could be observed and utilized to investigate the cavitation severity of the MHVs.

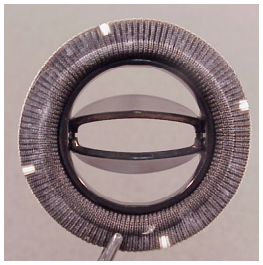
Materials & Methods

As shown in Figure 1, a 20-mm Björk-Shiley and the FDA Round Robin 27-mm MHVs (Medtronic-Hall, Edwards-Duromedics and St Jude Medical) were examined for MHV specimens [6]. A simple pressure pulse duplicator was used. This system simulates opening and closing events of the MHV in the mitral position. The system was composed of an air compressor, an air pressure regulator, solenoid valves, and a MHV mounting chamber (Figure 2). The solenoid valves were controlled to adjust the frequency of the valve movement (the heart rate) and the loading and ventilation periods. The system was operated by the regulated bursts of the compressed air through the action of the solenoid valves. A burst cycle was composed of the loading and ventilation periods. The heart rate was set to 60 bpm, and 30% loading and 70% ventilation periods were used. Closing and opening events of the MHV were repeated alternately in the experiments. The negative peak pressure (NPP) detected on the inflow side of the MHV was used for the signal of the valve closure, and a high frequency pressure transducer (105C02, PCB Piezotronics, Inc., USA) was adopted for the detection of the NPP.

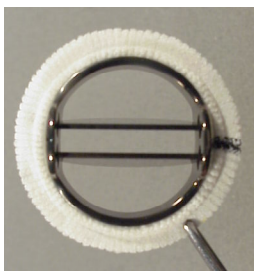
(a) 20-mm Björk-Shiley



(b) 27-mm Medtronic-Hall



(c) 27-mm Edwards-Duromedics



(d) 27-mm St Jude Medical

Figure 1: MHV specimens tested in this study.

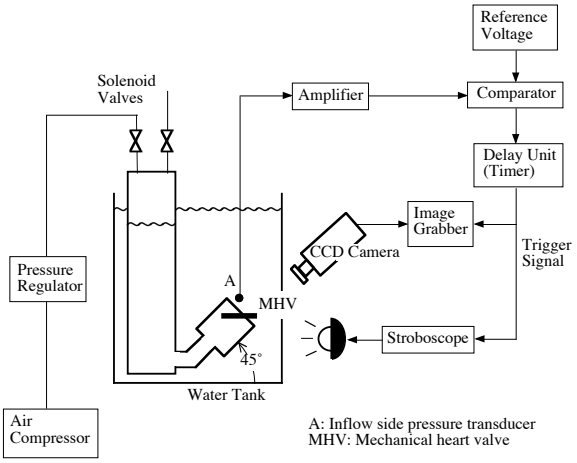


Figure 2: Schematic diagram of the pressure pulse duplicator for capturing photographic images with a stroboscope.

First, submerging the MHV specimen in deionized water, photographic images were captured using a stroboscope (Figure 2). According to these photographic observations, the occurrence of cavitation was confirmed for each specimen. The stroboscopic method is the simplest method to get still pictures of cavitation bubbles, and in this study the images were captured using a stroboscope (FA-1J-10, Nissin Electronic Co., Ltd, Japan) and a CCD (charge coupled device) camera (WAT-103, Watec Co., Ltd., Japan).

Second, a photomultiplier tube (PMT) (H7360-01, Hamamatsu Photonics, Japan) was applied to capture the violent bubble collapse by observing sonoluminescence around MHVs. For the observation of sonoluminescence, the whole apparatus was settled in the lighttight box to minimize the background noise. The MHV mounting chamber with a valve specimen was submerged in the water tank, and the optical window that passes UV light was prepared on the wall of the water tank to detect sonoluminescence from the cavitation bubbles. The configuration of the observation system using a PMT is shown in Figure 3. As a blood analog, 9-L deionized water was used.

Then, the detection of sonoluminescence was tried in *in vitro* blood testing for a 20-mm Björk-Shiley and a 27-mm Medtronic-Hall. To reduce the amount of blood required for tests, a small water tank of 2.5 liter was prepared. Goat blood was diluted with isotonic saline to 5 vol%. To enhance the light emission, xenon gas was introduced into the fluid through bubbling [17,18].

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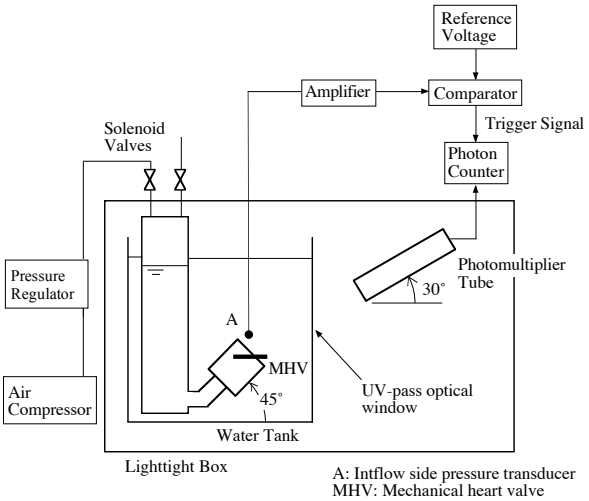
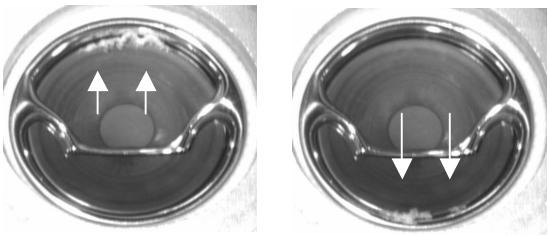


Figure 3: Schematic diagram of the pressure pulse duplicator for detecting sonoluminescence. The whole system was settled in the lighttight box.

Results and Discussion

Cavitation bubbles on a Björk-Shiley occurred both in its major and minor orifices on the inflow side (Figure 4). Bubbles in the major orifice were observed 500–750 μsec after the valve closure, and bubbles in the minor orifice were observed 800–1000 μsec after the valve closure.



(a) (b)

Figure 4: Photographic images of cavitation bubbles on a 20-mm Björk-Shiley: (a) bubbles in the major orifice and (b) bubbles in the minor orifice.

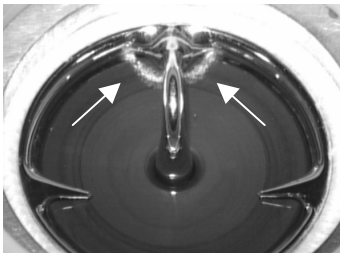


Figure 5: Photographic image of cavitation bubbles on a 27-mm Medtronic-Hall valve.

Bubbles on a Medtronic-Hall appeared soon after the valve closure, and they were observed up to 500 μsec after the valve closure (Figure 5). At closure the leaflet struck the struts. Using a high-speed camera, a jet came from the narrow gap between the leaflet and the strut, and it grew to the cavitation bubbles (data not shown to save space).

Bubbles on an Edwards-Duromedics were observed 0–300 μsec after the valve closure (Figure 6). Along the tip of the leaflet, there existed many small bubbles. Using our test loop, it was most difficult to capture the bubbles on a St Jude Medical valve because there were only a small number of bubbles and their lifetime was very short (Figure 7).

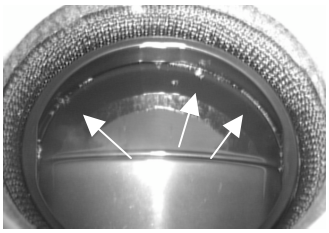


Figure 6: Photographic image of cavitation bubbles on a 27-mm Edwards-Duromedics valve.

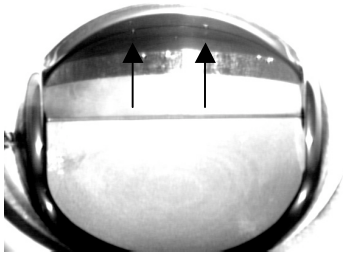


Figure 7: Photographic image of cavitation bubbles on a 27-mm St Jude Medical valve.

Using a PMT, sonoluminescence was observed for all MHV specimens. The pressure difference of 120 mmHg was exerted on each specimen. The photons were integrated over 500 beats, and they were recorded with respect to the elapsed time from the valve closure. The background noise was subtracted from the original photon count, and this modified photon count was plotted in the vertical axis (Figure 8).

The light emission pattern varied for each valve specimen. Comparing the results shown in Figure 4 and Figure 8(a), the two peaks of light emission on Figure 8(a) occurred soon after the bubbles in Figure 4 disappeared. This is one of proofs that we were observing sonoluminescence from collapsing cavities. Detailed discussions about the source of the faint light were made for a Björk-Shiley valve in our previous studies. The spatial distribution of light emission was observed for a 20-mm Björk-Shiley valve using a highly sensitive CCD camera with an image intensifier, and sonoluminescence was observed at the same positions of

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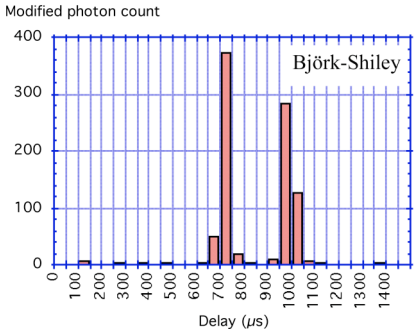
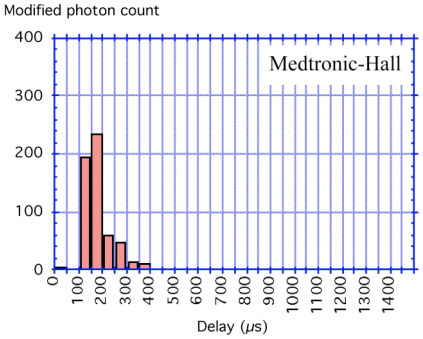
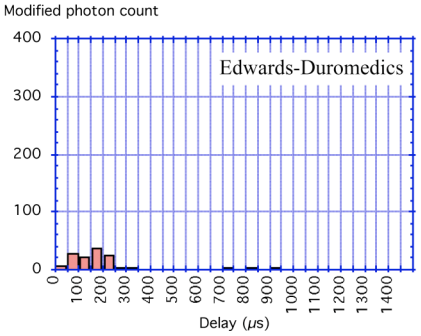
the cavitation bubbles captured with a stroboscope (see Figures 3–5 in reference [19]). Judging from the spatiotemporal distribution of light emission on a Björk-Shiley, we concluded that the light came from the collapsing bubbles [20].



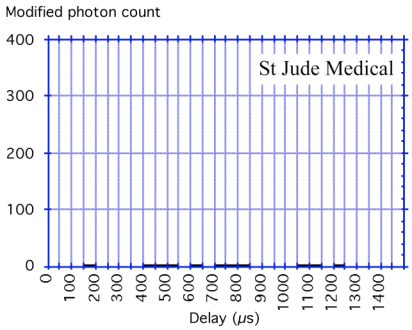
(a) 20-mm Björk-Shiley



(b) 27-mm Medtronic-Hall



(c) 27-mm Edwards-Duromedics



(d) 27-mm St Jude Medical

Figure 8: Light emission pattern of tested valve specimens. Modified photon count was plotted against the delay from valve closure.

A similar observation was repeated for the driving pressure of 200 mmHg, and the total photon counts for 3.5 msec from valve closure were calculated. The results for the driving pressure of 120 and 200 mmHg were summarized in terms of *the cavitation intensity* to simplify the comparison of the cavitation potential of the tested MHVs. Here, the ratio of the total photon count for a MHV specimen to that for the 20-mm Björk-Shiley valve against 120 mmHg was defined as *the cavitation intensity*. The result shown in Figure 9 is, on the whole, acceptable and it clearly demonstrates that bileaflet MHVs elude severe cavitation.

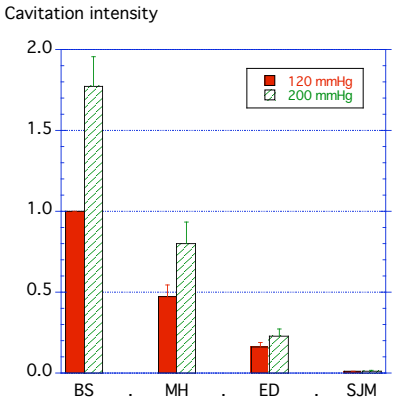


Figure 9: Cavitation intensity of tested valve specimens. BS, Björk-Shiley; MH, Medtronic Hall; ED, Edwards-Duromedics; SJM, St Jude Medical. Error bar length is the standard deviation. BS against 120 mmHg is the reference condition.

The detection of sonoluminescence was tried through blood. Because the faint light could be absorbed and scattered through blood, sonoluminescence should be amplified for observation. In this study, xenon gas bubbling into blood was adopted to enhance light emission. First, the effect of xenon was confirmed using a 20-mm Björk-Shiley valve in deionized water. The result is shown in Figure 10. The light emission increased approximately 60-fold due to xenon.

Then, the detection of sonoluminescence was tried in *in vitro* blood testing. To reduce the amount of blood required for tests, a small water tank of 2.5 liter was prepared. Goat blood was diluted with isotonic saline to 5 vol%. To enhance the light emission, xenon gas was introduced into the fluid through bubbling. A 20-mm Björk-Shiley and a 27-mm Medtronic-Hall valves were tested, and the driving pressure of 120–300 mmHg was exerted on each specimen. The total photon count for 3.5 msec from valve closure was plotted against the driving pressure. Each measurement was the integration over 500 beats (Figure 11).

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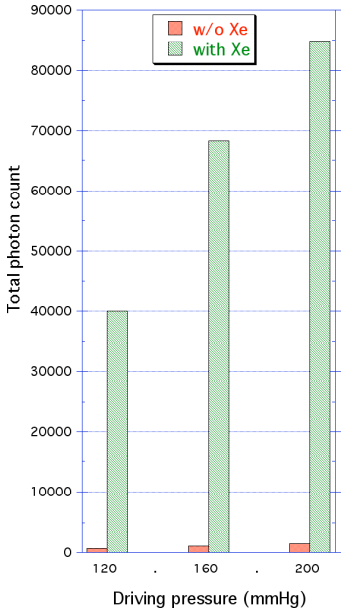
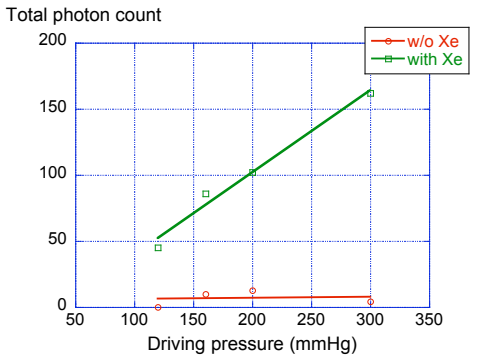
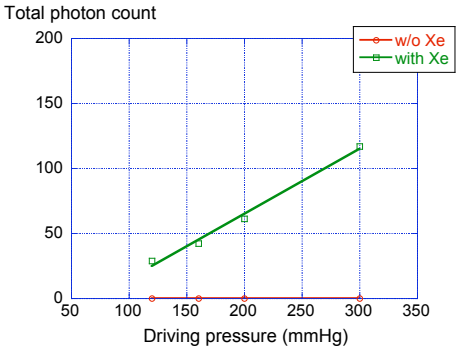


Figure 10: Effect of xenon gas on sonoluminescence from cavitation bubbles around a 20-mm Björk-Shiley. Xenon gas enhanced the light emission about 60-fold.



(a) 20-mm Björk-Shiley



(b) 27-mm Medtronic-Hall

Figure 11: Result of *in vitro* blood test for Björk-Shiley and Medtronic-Hall valves.

The light enhancement due to xenon gas is obvious also in the blood tests. For blood samples, almost no light was observed without xenon. Although the diluted blood absorbed and scattered the light from the cavitation bubbles, xenon gas augmented sonoluminescence sufficiently and it was detected with a PMT outside the water tank. The total photon count was dependent on the driving pressure. Higher driving pressure induced more photon emission, *i.e.*, more severe cavitation. From the results shown in Figure 11, more sever cavitation damage would be caused on the Björk-Shiley valve.

Conclusion

Comparing the photographic images with faint light observations, the behavior of the cavitation bubble implosion around MHVs was successfully observed based on sonoluminescence. Based on the total photon count observed, *the cavitation intensity* was introduced, and it was clearly demonstarated that bileaflet MHVs elude violent cavity collapse. We believe this method would be acknowledged for gauging the MHV cavitation severity.

One of the difficulties of observing sonoluminescence was too faint light to apply it to *in vitro* blood testing. For blood samples, no light could be observed without xenon. Xenon gas, thus, effectively amplified sonoluminescence, so that it was observed even in blood samples. This amplification using xenon might enable future *in vivo* observation of sonoluminescence from cavitation bubbles on MHVs, because xenon gas can be used as an anesthetic as well as a light-enhancing agent.

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