Evaluation of a Ventricular Assist Device: Stability Under X-Rays and Therapeutic Beam Attenuation

Michael S. Gossman,* Joel D. Graham,† Dan Tamez,† Neil Voskoboynikov,† and Jeffrey A. Larose†

Improved outcomes and quality of life of heart failure patients have been reported with the use of left ventricular assist devices (LVADs). However, little information exists regarding devices in patients undergoing radiation cancer treatment. Two HeartWare Ventricular Assist Device (HVAD) pumps were repeatedly irradiated with high intensity 18 MV x-rays to a dosage range of 64–75 Gy at a rate of 6 Gy/min from a radiation oncology particle accelerator to determine operational stability. Pump parameter data was collected through a data acquisition system. Second, a computerized tomography (CT) scan was taken of the device, and a treatment planning computer estimated characteristics of dose scattering and attenuation. Results were then compared with actual radiation measurements. The devices exhibited no changes in pump operation during the procedure, though the titanium components of the HVAD markedly attenuate the therapy beam. Computer modeling indicated an 11.8% dose change in the absorbed dosage that was distinctly less than the 84% dose change measured with detectors. Simulated and measured scattering processes were negligible. Computer modeling underestimates pretreatment dose to patients when the device is in the field of radiation. Future x-ray radiation dosimetry and treatment planning in HVAD patients should be carefully managed by radiation oncology specialists. *ASAIO Journal* 2012; 58:212–216.

The implantation of continuous flow left ventricular assist devices (LVADs) for support of heart failure patients has seen a remarkable growth in the last decade. Patients have enjoyed improved outcomes and quality of life from advances in this technology.[1–3] Contraindications for implantation of an LVAD in treatment enrollment include patients undergoing cancer treatment. However, discovery of malignant cancers may occur after implantation of the device. Currently, there is minimal information on the effects of radiation exposure on device operation. As this population segment increases, radiation oncologists will have to be prepared to treat potential cancer patients who have an implanted LVAD.

The interest of this study was twofold. First, it sought to address whether any electronic instability in the HeartWare Ventricular Assist Device (HVAD) pump (HeartWare, Inc., Miami Lakes, FL) could be measured when directly irradiated from megavoltage x-rays provided by a radiation oncology particle accelerator. Previous research has seen instability for devices such as implantable pacemakers and cardioverter-defibrillators (ICDs).[4,5] Second, a computed tomography (CT) scan was taken of the device and a treatment planning computer[6–8] estimated characteristics of dose scattering and attenuation of the device. Radiation measurements were then compared with the results modeled on computer. The results from these studies are aimed at supporting radiation oncology specialists in treating patients implanted with the HeartWare HVAD pump. (The HeartWare HVAD is currently an investigational device restricted by US law to investigational use only.)

Materials and Methods

Two HeartWare HVAD pumps were tested for device stability and therapeutic beam attenuation. The HVAD pump is a continuous flow mechanical assist device implanted in heart failure patients as a bridge to transplant or in some cases as long-term destination therapy (DT). The pump is directly inserted into the patient's failing ventricle and provides centrifugal flow through a wide-blade impeller design. The HeartWare ventricular assist system comprises the implanted HVAD pump, which is connected through a percutaneous driveline to a system controller powered through two power sources.[9] The testing chamber was composed of a CNMC Company, Inc. (Nashville, TN) model WP-3040 tank that was filled to a depth of 20 cm with water. Stacked plates totaling 8 cm of acrylic were then adhesively affixed to the bottom surface of the tank. The HVAD pump was then immersed in the water phantom and strapped to the platform at a depth of 12 cm.

Stability Testing

The testing chamber was placed on the table of the Varian Medical Systems, Inc. (Palo Alto, CA) model 21EX particle accelerator. The gantry arm was rotated to an incident angle of 270°, simulating the typical positioning expected for an implanted patient. Radiation entered through the side of the phantom laterally toward the pump at a distance of 12 cm. The distance from the source to this location was 100 cm, as verified by in-room lasers mounted on the vault walls. Radiation dose was measured at this point. The particle accelerator

From the *Tri-State Regional Cancer Center, Radiation Oncology Department, Ashland, Kentucky; and †HeartWare, Inc., Miami Lakes, Florida.

Submitted for consideration September 2011; accepted for publication in revised form December 2011.

Disclosure: The authors have no conflicts of interest to report.

Reprint Requests: Michael S. Gossman, MS, DABR, Tri-State Regional Cancer Center, Radiation Oncology Department, 706 23rd St, Ashland, KY 41101. Email: mgossman@tsrcc.com.

DOI: 10.1097/MAT.0b013e3182468318

was programmed to deliver 18 MV pulsed x-ray radiation at a dose rate of 6 Gy/min. A single beam, having a 30 × 30 cm^2 aperture, was applied. The HVAD pump was connected to the system controller and powered with two battery sources. The pump was programmed to operate under normal operating guidelines and was set to a speed of 2,400 RPM. Pump parameters including power, speed, and estimated volumetric flow rate were collected and analyzed with a custom clinical data acquisition system at a frequency of 50 Hz.

Stability testing was conducted at doses deemed clinically relevant in application to lung cancer patients, as this would likely present a larger challenge in treatment planning than would other sites of disease occurrence. Lung cancer treatment prescriptions differ depending on the classification and staging of the disease. A typical non–small-cell lung cancer patient staged 1b (T2aN0M0) may be given 66 Gy, whereas one with the same disease type staged X (T2N0M0) may be prescribed 74 Gy. Common dosages delivered to lung cancer patients in x-ray radiation treatments are 60–74 Gy. The setup for the stability testing is presented in **Figure 1**.

Computer Modeling and Treatment Planning

The same testing chamber was used for treatment planning. The HVAD pump was disconnected from the system controller and was not powered for this phase of testing. The pump was scanned and radiation measurements were taken as described. Computer modeling results from the treatment planning system were compared with actual measurements.

CT scan acquisition. Computed tomography scan acquisition was conducted using a General Electric (Fairfield, CT) LightSpeed RT scanner. The helical mode stereotactic radiosurgery technique included 120 kVp x-rays at 340 mA for 86 seconds. A total of 254 scan slices defined the image set sent to the treatment planning system. Each slice was spaced 1.25 mm/slice and corrected for extended Hounsfield unit range.[10]

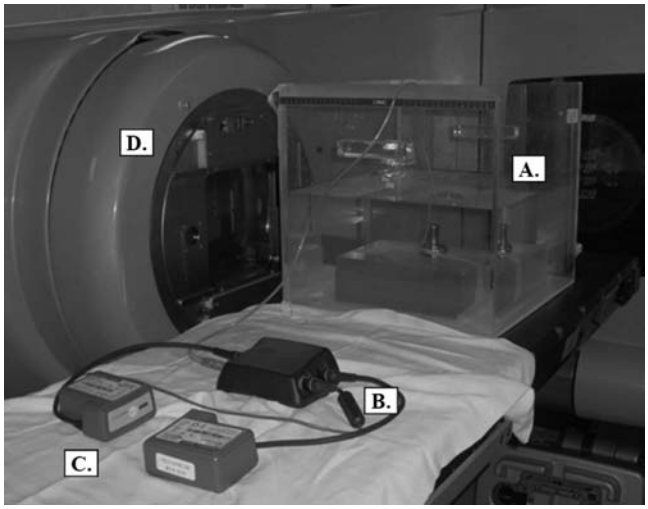

Figure 1. Stability testing of the HVAD pump in phantom media on the table of the particle accelerator including (**A**) HVAD submerged in testing chamber, (**B**) system controller, (**C**) batteries, and (**D**) particle accelerator gantry.

Dose computation. Varian model Eclipse treatment planning system, version 8.6 (HeartWare, Inc., Miami Lakes, FL) with the anisotropic analytical algorithm was used for dose modeling. This software is used clinically as a means of estimating dose delivery before irradiation through measurement from the 21EX particle accelerator. Approximations to the dose delivery are illustrated within the software for a patient's CT anatomy. Similarly, the water phantom CT scans containing the HVAD pump model an implanted patient. Image artifacts were removed using Boolean operation as described in the literature. A single 18 MV x-ray beam having gantry angle 270˚ was applied as used previously in electronic stability testing. The aperture was 30 × 30 cm^2 with a dose rate of 600 MU/min. The isocenter chosen for dose calculation was the location where the device driveline enters the pump. Dose calculation points were dispersed around the device at distances varying from 1 to 3 cm away. Two types of dose computations were performed. First, a 3D calculation was made assuming all media to be composed only of water. Then, the computer was set to provide dose results with density correction applied so as to account for the interaction of the submerged HVAD pump with the incident x-rays. The ratio of absorbed dose at each point in the two plan types gives rise to the overall effect of having the pump in the beam. Dose data from points interiorly more near to the beam represent backscattering, whereas lateral points represent side scattering. Finally, point doses determined beyond the HVAD pump detail attenuated intensity.

Radiation measurement. Measurements were performed for scatter dose using a similar phantom setup. With the HVAD pump submerged, point measurements were taken using a Wellhofer-Scanditronix (Bartlett, TN) Farmer-type ionization chamber model TN31014. The thimble chamber was connected to a CNMC Company model 206-110 electrometer with charge range element that equilibrated the chamber to nominally +300 V at the center-pin. Having a sensitive volume 0.015 cm^3, the water-resistant "pin-point" detector was placed at each of the planned point locations near the HVAD pump at scattering locations upstream and laterally. The Sun Nuclear (Melbourne, FL) model MapCheck provided attenuation measurements beyond the pump. The MapCheck 2D diode array contains 445 N-type diodes, all embedded in 2 cm of water-equivalent plastic and variably spaced 22 × 22 cm^2 in area. As the diode array cannot be placed in water, a setup change was necessary. The acrylic plates were removed from the water phantom entirely. Then the HVAD pump was set on the bottom of the tank. The tank was raised and leveled immediately on top of the MapCheck diode array. The HVAD pump was reoriented in the direction of a beam set to be 180°. All attenuation measurements were taken at 3 cm distance from the HVAD pump. Pulsed radiation was given at a dose rate of 6 Gy/min identically.

Results

Stability Testing

The HVAD pump revealed no real-time operational changes at doses up to 75.6 Gy in the first device or up to 64.2 Gy in the second device. There were no changes seen with the beam on, even in the wake of multiple beam interruptions where the intensity was intentionally stopped and restarted quickly to simulate radiation intensity modulation. Likewise, there

Table 1. HVAD Parameters for Both Pumps of Operation During Stability Testing

Pump Parameters	Avg ± SD
Power (W)	3.3 ± 0.2
Estimated flow (L/min)	5.9 ± 0.6
Speed (RPM)	2400 ± 8

SD, standard deviation; Avg, average.

were no noted changes as a result of cumulative dose. **Table 1** provides the average pump parameters for both pumps. The principal focus of the radiation beam was directed to the area where the driveline wires enter the pump as this is the most critical place where a problem could occur. Visual observation after irradiation of both pumps showed no discoloration in the driveline or in the surrounding area where the wires enter the pump. Minimal fluctuations were seen in real-time monitoring of pump parameters. Sample data are provided as observed during testing in **Figure 2**. This 30 second window shows minimal fluctuations in power (W), speed (RPM), and estimated flow (L/min) during radiation exposure. Review of the system controller log files showed no alarms or events triggered during device operation.

Computer Modeling and Treatment Planning

Computer modeling showed no significant dose change with the HVAD pump in the beam from scattering processes. Only minor changes were noted as 1.5% for backscattering and 0.5% for side scattering. However, beam blocking was remarkable at 11.8% attenuation. **Figure 3** plots dose change exhibited with the HVAD pump in the beam path. Significant absorption of dose is identified immediately after the device where isodose lines have shifted toward the pump. Without the pump in the tank, each line was straight from one field edge to the other across the profile.

Point dose measurements from the Farmer-type chamber were insignificant for scatter results. Backscattering was found to be 2.0% and side scattering was slightly less at 1.2%. Attenuation measurements made with the MapCheck diode array were significant. A peak of 84% beam blocking was measured by one diode, which was confirmed by other local diodes at nearly the same maximum change. **Table 2** provides the results from both the calculated and measured dosage. The calculated treatment plan underestimated dosage delivery compared with the actual measured scattering and attenuation.

Discussion

This study is the first report on the direct effects of radiation beams on ventricular assist device (VAD) operation as only one case report is in the current literature.[11] The primary findings of this *in vitro* stability study report is that the HVAD pump was not affected by radiation exposure at clinically relevant dose and that current treatment planning software underestimated dosage delivery. Although the commercial treatment planning system was capable of providing the direction of the change in dose, it drastically underestimated the true measured affect for attenuation. This difference between calculated and measured dose should not be surprising considering the construction of the HVAD pump. The housing of the pump is composed of a hybrid, titanium ceramic assembly with the impeller containing large rare-earth motor magnets.[9] The attenuation and scattering measured match magnitude changes expected for materials made from titanium.

This study provided a maximal dosage applied at a frequent number of iterations, though it could not predict the true long-term effects of prolonged radiation treatment. A possible accumulating effect from frequent treatments could increase sensitivity of the HVAD system. Studies done on the effect of therapy on other implantable devices such as pacemakers and ICDs have shown that radiation can debilitate and affect device function with reported malfunctions that can occur days after treatment.[12] This is primarily because of the effect the direct therapy beam has on sensitive electronic devices, most notably capacitors and transistors. Another limitation was in the small sample size (n = 2), though this was primarily a feasibility test. Further testing with a larger number of systems is needed.

All the electrical components of the HVAD system are housed in the system controller. The microprocessor based system controller connects to the pump via a percutaneous driveline that operates the pump, manages power sources, monitors pump function, provides diagnostic information, and stores pump parameter data.[9] The HVAD pump is the only part of the system in the direct path of the beam and does not contain the sensitive

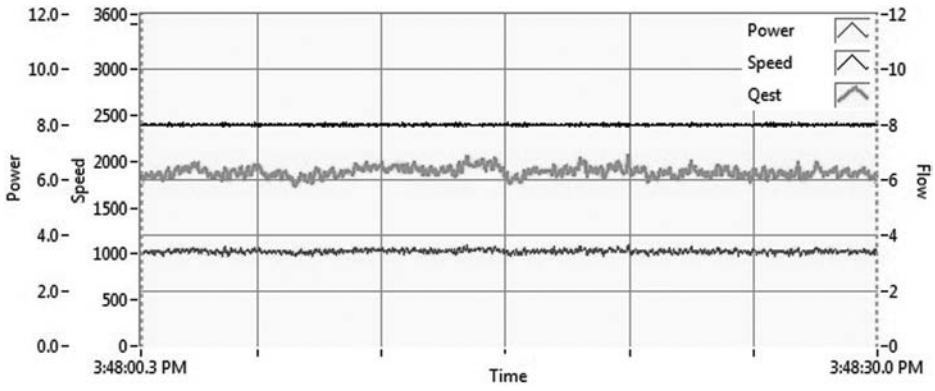

Figure 2. Pump parameter waveform data captured during HVAD pump stability testing. Stability testing of the HVAD pump under the duress of high energy x-rays and high intensity revealed no effect on either pump.

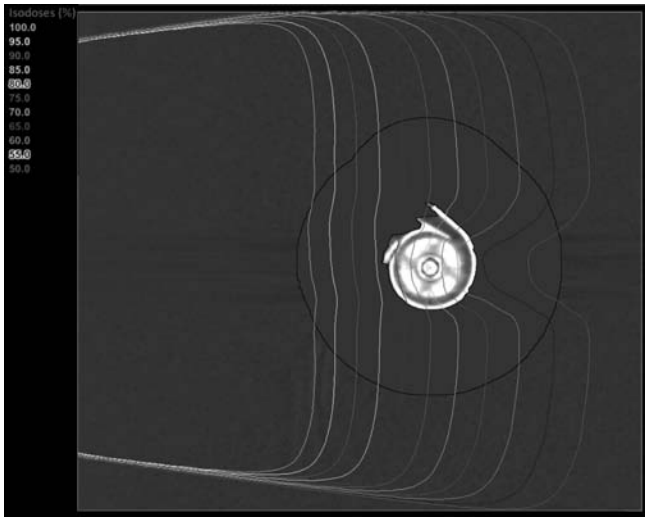

Figure 3. Treatment planning simulation detailing isodose line gradients beyond the HVAD pump. This view provides a cross-section of the HVAD seen from top looking down into the inflow with the device impeller and flow volute visible.

components that frequently interfere with functionality. In a typical treatment procedure for a patient, the system controller is outside the therapeutic beam area (seen in **Figure 2**). If interference of device function is observed in a clinical setting from radiation treatments, the system controller may simply be replaced. This interchangeability of the system controller provides an added factor of safety to the procedure.

As no consequences were identified for the 18 MV x-ray beam at a dose rate of 6 Gy/min, no consequences should be identifiable for x-rays of lesser energy or at lower dose rates. With the use of the 18 MV x-ray beam, neutron radiation is known to have been generated. Neutrons are not significantly generated at energies below 10 MV in general.[13] Even though the x-rays were directly incident upon each device, neutrons exist as a secondary radiation consequential to this bombardment.[4] Therefore, the result of a null effect from 18 MV x-rays is really null effect verification from the combination of x-ray and neutron radiation on the pump. We noted that this did not provide a definite immunity to neutrons in this regard, because neutron radiation was not of high intensity and was not directly aimed at the device.

As this experiment was completed in a large tank, the typical physiologic preload and afterload conditions in which the HVAD operates in the human body were not replicated. This allowed the pump to flow at >5 L/min at a lower pump speed setting. Still, the important finding was no observed relative change in power or speed operation was observed under exposure to incident radiation.

We suggest careful management of radiation oncology treatments in VAD patients. As the scattering properties of the device were minimal and no device interactions were measured, direct treatment of tissue surrounding the device was feasible. However, treatment planning for tissue behind the device should be avoided because of the attenuation properties of the titanium components. In these cases where the device is in the direct path between the beam source and the targeted tissue, a different beam angle that does not go through the device is warranted.[14] If a treatment plan with the beam going through the device is unavoidable, then an appropriate change in dosage is needed to effectually deliver treatment.

Table 2. Results from Scattering and Attenuation

	Backscatter (%)	Side Scatter (%)	Attenuation (%)
Computed	1.5	0.5	12
Measured	2.0	1.2	*84

*Peak ionization chamber point dose measurement.

Conclusions

The growth in implantation of continuous flow VADs will continue to rise as the number of heart failure patients increases worldwide. With the limited number of donor hearts available for transplantation and the increase of DT, clinicians will be relying on longer-term support from mechanical assist devices. With this growth, the prevalence of treatment of cancer in patients implanted with VADs will increase. Cardiovascular physicians along with radiation oncologists will need to be prepared to serve this patient population. Although this was a small study (n = 2), the pumps showed no change in device operation because of radiation damage under the highest therapeutic x-ray energy available on a particle accelerator and under the highest dose rate possible. Second, computer modeling of irradiation affects were underestimated in comparison with true measured dose. Radiation oncologists and medical physicists should be cautioned about the lack of accuracy in such computer modeling when relying on CT scan acquisition images with patients implanted with a VAD.

Acknowledgment

Supported by an industry contract with HeartWare, Inc.

REFERENCES

1. Rogers JG, Aaronson KD, Boyle AJ, *et al*: Continuous flow left ventricular assist device improves functional capacity and quality of life of advanced heart failure patients. *J Am Coll Cardiol* 55: 1826–1834, 2010.
2. Kirklin J, Naftel D, Kormos R, *et al*: Third INTERMACS Annual Report: The evolution of destination therapy in the United States. *J Heart Lung Transplant* 30: 115–123, 2011.
3. Pagani FD, Miller LW, Russell SD, *et al*: Extended mechanical circulatory support with a continuous-flow rotary left ventricular assist device. *J Am Coll Cardiol* 54: 312–321, 2009.
4. Wilkinson JD, Bounds C, Brown T, *et al*: Cancer-radiotherapy equipment as a cause of soft errors in electronic equipment. *IEEE Trans Dev Mat Rel* 5: 449–451, 2005.
5. Hirose M, Tachikawa K, Ozaki M, *et al*: X-ray radiation causes electromagnetic interference in implantable cardiac pacemakers. *Pacing Clin Electrophys* 33: 1174–1181, 2010.
6. Gossman MS. Radiation oncology dose gradients induced by heart rhythm devices. *Diagnostic & Interventional Cardiology Magazine – Advances in Radiation Oncology*. March 1–5, 2011.
7. Gossman MS, Graves-Calhoun AR, Wilkinson JD: Establishing radiation therapy treatment planning effects involving implantable pacemakers and implantable cardioverter-defibrillators. *J Appl Clin Med Phys* 11: 3115, 2010.
8. Gossman MS, Seuntjens JP, Serban MM, *et al*: Dosimetric effects near implanted vascular access ports: An examination of external photon beam calculation. *J Appl Clin Med Phys* 10: 2886, 2009.

9. Larose JA, Tamez D, Ashenuga M, Reyes C: Design concepts and principle of operation of the HeartWare ventricular assist system. *ASAIO J* 56: 285–289, 2010.
10. Coolens C, Childs PJ: Calibration of CT Hounsfield units for radiotherapy treatment planning of patients with metallic hip prostheses: The use of the extended CT-scale. *Phys Med Biol* 48: 1591–1603, 2003.
11. Lasher DE, Wojcicka JB, Malcom R, Shears LL: Case study of radiation therapy treatment of a patient with a cardiac ventricular assist device. *J Appl Clin Med Phys* 9: 2851, 2008.
12. Hudson F, Coulshed D, D'Souza E, Baker C: Effect of radiation therapy on the latest generation of pacemakers and implantable cardioverter defibrillators: A systematic review. *J Med Imaging Radiat Oncol* 54: 53–61, 2010.
13. Reft CS, Runkel-Muller R, Myrianthopoulos L: *In vivo* and phantom measurements of the secondary photon and neutron doses for prostate patients undergoing 18 MV IMRT. *Med Phys* 33: 3734–3742, 2006.
14. Gossman MS. Pacemakers - Book 2, in Vonend O, Eckert S (eds), *Chapter 9, Clinical Concerns for and Strategies with Pacemakers in Radiation Oncology*. InTech, Janeza Trdine, Rijeka, Croatia, 2011: 145–162.