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BEAM PROFILE DISTURBANCES FROM IMPLANTABLE PACEMAKERS OR IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR INTERACTIONS

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Abstract—The medical community is advocating for progressive improvement in the design of implantable cardioverter-defibrillators and implantable pacemakers to accommodate elevations in dose limitation criteria. With advancement already made for magnetic resonance imaging compatibility in some, a greater need is present to inform the radiation oncologist and medical physicist regarding treatment planning beam profile changes when such devices are in the field of a therapeutic radiation beam. Treatment plan modeling was conducted to simulate effects induced by Medtronic, Inc.–manufactured devices on therapeutic radiation beams. As a continuation of grant-supported research, we show that radial and transverse open beam profiles of a medical accelerator were altered when compared with profiles resulting when implantable pacemakers and cardioverter-defibrillators are placed directly in the beam. Results are markedly different between the 2 devices in the axial plane and the sagittal planes. Vast differences are also presented for the therapeutic beams at 6-MV and 18-MV x-ray energies. Maximum changes in percentage depth dose are observed for the implantable cardioverter-defibrillator as 9.3% at 6 MV and 10.1% at 18 MV, with worst distance to agreement of isodose lines at 2.3 cm and 1.3 cm, respectively. For the implantable pacemaker, the maximum changes in percentage depth dose were observed as 10.7% at 6 MV and 6.9% at 18 MV, with worst distance to agreement of isodose lines at 2.5 cm and 1.9 cm, respectively. No differences were discernible for the defibrillation leads and the pacing lead. © 2011 American Association of Medical Dosimetrists.

Key Words: **Defibrillator, Distance to agreement (DTA), Implantable cardioverter-defibrillators (ICD), Implantable, Medtronic, Pacemaker, Radiation, TG-34.**

INTRODUCTION

The first pacemaker was designed by John A. Hopps in 1949.[1] From efforts to follow by investigators, such as the 1961 Nobel Peace Prize recipient, Bernard Lown, and the team of Michel Mirowski and Morton Mower, the first ever implantable cardioverter-defibrillators (ICD) and implantable pacmakers (IPs) became possible 20 years after Hopps' artificial invention.[2–4] These devices are now well-known, highly recommended, and routinely implanted by electrophysiologists and cardiovascular physicians internationally. As with all electronic devices, there are limitations to their usefulness. Clinically, the device may at times present a limitation for other medical specialists. One such area is in the field of radiation oncology.

In vitro testing of devices in radiation beams have led to findings of stability and functionality changes.[5, 6] With the consideration to those inherent operational deviations, radiation oncologists are apprehensive about possible effects that may be detrimental to the patient if a device remained implanted and used during or after radiation therapy. This is important even for the initial computerized tomography (CT) image acquisition, from which diagnostic staging and treatment modeling is based.[7] Investigators hope to identify the electronic effects revealed by such cardiovascular devices through research already underway.[8,9] The results of such investigational work may shed new light on recommended dose limitations, whereby modern devices with radiation-hardened electronics and magnetic resonance imaging (MRI) compatibility provide greater potential capability for sustaining functionality at doses exceeding the American Association of Physicists in Medicine (AAPM) recommendations of under 2 Gy.[10] With the AAPM advocating to the United States Food and Drug Administration to assist in the promotion of education and training on these devices in radiation oncology, direct concerns regarding the affects of such devices on a therapeutic beam remain unpublished.[11] As the functional changes in the electronic devices are being examined elsewhere, we present a focus study on the effects of radiation therapy beam profile shifts though computerized modeling.

The grant-supported research compiled here presents data for the radiation oncologist and medical physicist to reference, as a guide to treatment planning for

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cancer patients who require radiation when the device is still intact and intended for use during radiation delivery or afterward. Attenuation, side scatter, and backscatter have already been presented in the literature by this principal investigator under key research grant support.[12] In that study, nearly identical physical effects were demonstrated for all implantable pacemakers. Indistinguishable phenomena were observed for all ICDs.[12] It then follows that only one device from each group is necessary for study here.[12] The required data presented is attentive to the magnitude and direction of shifts in therapeutic isodose depth dose curves caused by the introduction of an ICD and an IP. Axial and transverse beam profiles are analyzed at x-ray energies of 6 MV and 18 MV from a commercially available particle accelerator used to treat upwards of 60 patients per day for cancer therapy. This research constitutes results for more than two-thirds of all device families marketed by Medtronic, Inc.[12,13]

METHODS

Computerized tomography acquisition

A phantom was used to simulate a patient having a cardioverter-defibrillator or pacemaker implanted. The CNMC Company, Inc. (Nashville, TN) model WP-3040 water phantom was used for this purpose. The 12-gallon tank with longest dimension 40 cm defines the scanning volume for all CT data used. Acrylic plates were added to the bottom of the tank to provide a platform for devices to rest, while insuring adequate backscatter from the megavoltage x-rays to be modeled. Square plates 24.8 cm wide were stacked to a height of 8.0 cm inside the WP-3040 water phantom. The tank was then filled to raise the water level 5.6 cm above the surface of the acrylic platform. This depth is also adequate to achieve build-up of dose at both 6 MV and 18 MV therapeutic x-ray energies. The ICD or IP was affixed to the center of the acrylic platform consecutively for each CT scan. Identical geometry was maintained in the experimental setup for each.

The General Electric (Fairfield, CT) Lightspeed RT scanner provided CT acquisition data. Scanning commenced after the programming of the helical mode stereotactic radiosurgery protocol: 120 kVp at 278 mA and an 80-second nominal scan time with 1.25 mm couch increments. The largest field of view at 50 cm was used. This process was repeated for both devices included in the study.

The Medtronic, Inc. devices include the biventricular ICD Concerto model C154DWK (VVE-DDDR) using defibrillation lead model 6947, and the IP Versa model VEDR01 using single pacemaker lead model 5076. The ICD Concerto and IP Versa generators are illustrated in Fig. 1. The Concerto ICD is the larger of the two. It has an orthogonal face area of 6.9 × 5.1 cm and thickness of 1.5 cm. The Versa IP is 3.1 times smaller in volume and 1.6 times smaller in area, with orthogonal face dimensions of 4.5 × 4.8 cm and thickness of 0.8 cm.

Fig. 1. Studied here from left to right are Medtronic, Inc. ICD Concerto model C154DWK (VVE-DDDR) and IP Versa model VEDR01

Scan image acquisition was commissioned for use of the extended Hounsfield units (HU) range.[14] As discussed for published studies involving deep brain neurostimulator lead localization techniques, vascular access port imaging, and beam modeling, the extended HU ranges are important for the observance of high-density materials for submillimeter positioning accuracy specificity in neurosurgery, as well as for proper dose estimations in radiation oncology.[15, 16] The default range for the GE Lightspeed RT scanner is –1024 to +3071 HU. This differs substantially from its extended range of –31,743 to +31,743 HU. With the ICD found to contain iron, silver, and vanadium in the battery, and with aluminum in the high voltage capacitor, values of 3800 HU and 3000 HU result, respectfully. Although the IP device is smaller in all dimensions, the battery is composed of mainly iodine and iron, thus 8000 HU result for it. In addition, for the IP, a copper telemetry antenna is included in the design. The antenna alone yields 17,500 HU on average. These high-density areas are of focus for large isodose beam profile change locations, because doses will be computed with more attenuation and scatter for these high-density objects. Once each scan was reconstructed, the independent scan sets containing a total of 446 slices were transferred to a computer for dose calculation.

Dose computation

Dose delivery modeling was performed using the Varian Medical Systems, Inc. (Palo Alto, CA) Eclipse build version 8.6 external beam planning software. Artifacts were identified around each device, which occur as a consequence to improper sampling of attenuation data, from beam hardening of the 120-kVp CT beam through metal. With the beam incident only from the transverse direction, it then follows consistently with our findings that data streaking follows mainly lateral paths.

Dose computation in treatment planning with high-gradient false artifacts can result in miscalculation. Therefore, methods were suitably assigned to negate these observances.

Using existing knowledge of the dimensions of the ICD and IP, the software was used to carefully contour the surface area of each device on all CT slices. Then, a new structure was created using a Boolean operator, such that the new structure was identical in shape as the device scanned. A margin for the structure was programmed to increase its size by 3.5 cm. The new structure volume was then redefined using the Boolean tool, such that the resulting volume did not include the volume of the device being studied. The final new structure volume envelopes the ICD or IP device entirely with a margin of 3.5 cm and excludes the volume of the studied device within. An assignment of 0 HU for water density to this new structure, which encompassed the artifacts revealed in the CT dataset, ensured no analysis errors for dose computation.

Calculations of dose from these CT data were made possible by use of the Varian Medical Systems, Inc. anisotropic analytical algorithm (AAA) version 8/6/15, which incorporates ionization chamber–measured data from a medical accelerator used for treating patients. The algorithm was commissioned for use with the Varian Medical Systems, Inc. model 21EX high-energy particle accelerator with photon energies of 6 MV and 18 MV. The particle accelerator was calibrated in accordance with AAPM Task Group protocol 51 for an output of 0.01 Gy per monitor unit at the center of rotation of the machine.[17] The water depth providing maximum dose was nominally 1.5 cm at 6 MV and 2.5 cm at 18 MV. Varian scaling geometry was used, where the gantry angle, couch angle, and collimator were each at 180°. The beam size for calibration was a square $10 \times 10\text{-cm}^2$ field.

A single anterior field was assigned to pass through the center of the device in each of the identical plans. The beam target position was at the center of the device volume. Although the Boolean operator was used to remove illusory scatter contributions from artifacts around the device, scatter from the device will still be evident and important. Thus, the reference point for dose calculation was appropriately assigned to be 8.0 cm off-axis from the central ray, yet still at a depth of 3.5 cm, where adequate build-up is assured for both x-ray energies. The prescription for calculation was for the reference point to receive 2 Gy at 4 Gy/min. The radiation field was defined by $30 \times 30\text{-cm}^2$ jaw collimation, where ideal properties are seen for flatness and symmetry of the beam. The smallest possible dose calculation grid of 1.25 mm was assigned.

The AAA algorithm was first programmed to provide dose results simulating a phantom composed of only water density, including for the ICD or IP being used. Then, the algorithm was reprogrammed to provide dose results true for the various densities of all materials in the radiation field. The homogeneous plan represents the normal distribution of dose from the particle accelerator with nothing in the radiation field but water. The heterogeneous plan represents the isodose distribution when the ICD or IP is in the field of radiation additionally. Thus, remarkable results can be obtained when intercomparing the 2 planned dose distributions. The analysis method is consistent with published guidance of AAPM Task Group No. 63 for simulating dose involving high-atomic-number materials.[18]

The resulting 3-D distribution of dose absorbed by the phantom medium is shown in separate views of the software. Axial, coronal, and sagittal planes are visualized. The axial plane was chosen for use in the analysis because it detailed the results well for the anterior-superior directions and lateral directions. The superior-inferior directions are well visualized in the sagittal plane similarly, so it was also chosen. The coronal view shows results for the superior-inferior plane and lateral plane. Because nothing new is offered in this view, it was not used. The axial dose distribution was exported from the treatment planning system for further software examination. Likewise, the sagittal beam profile was sent. Exporting was conducted iteratively for both the homogeneity plan and heterogeneity plan, at both x-ray energies, and for both the ICD and IP.

The Sun Nuclear (Melbourne, FL) MapCheck software application version 5.00.00 was incorporated to analyze dose modeling results. The software has the capability of plotting the dose from 2 plans in any 1 particular plane.[19] Thus, where isodose distribution changes are seen to exist for the beam profile between the homogeneous plan and the heterogeneous plan, the superimposed plot will make known any notable shifts. Overlaying plots was conducted at 6 MV and at 18 MV for the ICD Concerto, then at 6 MV and 18 MV for the IP Versa.

Dose distribution analysis

A Van Dyk distance to agreement (DTA) analysis was performed on each overlay plot.[20,21] Letting $\Delta\%DD_{HM,HT}$ be the percentage depth dose (%DD) difference between the homogeneous plan profile result ($\%DD_{HM}$) and the heterogeneous plan profile result ($\%DD_{HT}$) and with C_{Norm} given as the normalization value at the reference point of interest, the formula for the Van Dyk DTA is shown as Eq (1).

$$\Delta\%DD_{HM,HT} = 100\left(\frac{\%DD_{HT} - \%DD_{HM}}{C_{Norm}}\right) \quad (1)$$

This analysis determines what percentage of dose change was exhibited in the beam profile when the ICD or IP are introduced in the beam. Likewise, the physical shift length DTA was calculated letting (L_{HM}) be the homogeneous plan profile result position, letting (L_{HT})

be the heterogeneous plan profile result position, and with C_{Norm} given as the normalization value at the reference point of interest. The formula for the DTA at the %DD of interest is shown as Eq (2).

$$DTA_{HM,HT} = \left(\frac{L_{HT} - L_{HM}}{C_{Norm}} \right) \quad (2)$$

The routine is carried out and presented for the maximum change in the beam profile percentage depth dose as well as for the maximum measured distance to agreement in centimeters at that maximum. The computations were executed for both the ICD and IP at both x-ray energies stated. The location of shifts are noted and compared between the 2 devices in both the axial and sagittal planes.

RESULTS AND DISCUSSION

Isodose distribution overlay plots for the ICD Concerto are presented in Fig. 2 for both 6 MV and 18 MV. The beam profile for the homogeneous density dose distribution and the heterogeneous density dose distribution are evident. The normal beam profile is flat and symmetric. With the device in the center of the field, it is observable what impact it has on the distribution to dose.

For the ICD, the shifts in depth dose are seen to be nearly uniformly occurring in the lateral direction as viewed in the axial plane. This is consistent with the design of the high-density battery and capacitor extending both from one side to the other. However, more shifting in the profile is noted in the superior direction compared with the inferior direction in the sagittal view. This indicates that the battery is composed of higher-density metal than that of the capacitor and that the battery placement within the device is superior. Results here are also consistent with the HU magnitudes concluded from CT scan acquisition. Again, the battery registered 3800 HU for the battery, whereas the high-voltage capacitor registered only 3000 HU. No differences were evident through dose simulation for the defibrillation leads.

Isodose distribution overlay plots for the IP Versa are presented in Fig. 3 for both 6 MV and 18 MV. The beam profile isodose swing in each of the beam profiles is even more evident for the IP and occurs in different directions relative to the ICD. In the axial plane, the indication is a greater shift laterally to the left than to the right. Reviewing the construction details of the device, this is consistent with lateral left-sided placement of the battery. Also consistent with CT scan data, the IP battery registered 8000 along with an abutting telemetry antenna at 17,500 HU laterally left. In the sagittal plane, the beam profile relocation is centrally located. It is understood, because the battery for the pacemaker spans the superior-inferior length of the device. No differences were noticeable through dose simulation for the pacing lead.

The beam profile changes are noted in percentage according to the isodose color chart provided. Each level represents the percentage of the dose prescription of 2 Gy that was modeled on the computer. The most significant changes occur between mainly 70% and 80% and 80% and 90% isodose lines. The upward shift in the distribution indicates that a larger amount of absorbed dose is attributed to the device being present. In the same way, this is an indication of a considerable amount of attenuation of the beam intensity. There is a negligible difference in the form of the profile change between 6- and 18-MV energies. The Van Dyk DTA analysis is quite distinguishable between the two for each device. Data results are presented in Table 1.

The maximum change in the %DD profile for the Concerto ICD at 6 MV was 5.3% in the axial plane and 9.3% in the sagittal plane. DTA analysis maximum results there indicated 1.3 cm and 2.3 cm %DD change, respectively. At 18 MV, the maximum Δ%DD was 3.6% viewed axially and 10.1% viewed sagittally. DTA analysis indicated 1.0-cm and 1.3-cm changes, respectively.

The maximum change in the %DD profile for the Versa IP at 6 MV was 10.0% in the axial plane and 10.7% in the sagittal plane. DTA analysis maximum results there indicated 2.3-cm and 2.5-cm %DD change, respectively. At 18 MV, the maximum Δ%DD was 6.9% viewed axially and 6.3% viewed sagittally. DTA analysis indicated 1.9-cm and 1.8-cm changes, respectively.

CONCLUSION

With advances such as MRI compatibility, which have now been achievable for some cardiovascular stimulation devices, the clinical community is now advocating for more progressive improvement in design to accommodate elevations in dose limitation criteria, where higher doses may hopefully be permitted to such devices without alteration of their electrical functionality and stability. Specifically, an increased interest is now being seen with regard to radiation therapy dose effects when a device is near or directly in the field of a therapeutic beam. Here, we present information of interest directly to the radiation oncologist and medical physicist regarding treatment planning beam profile changes when IPs and ICDs are in the field of radiation.

Treatment plan modeling was conducted to simulate effects on treatment beams induced by Medtronic, Inc. manufactured devices. As a continuation of grant-supported research, we show that radial and transverse open-beam profiles of a medical accelerator were altered when compared with profiles resulting when IPs and ICDs are placed directly in the beam. Results are markedly different between the 2 devices in the axial and the sagittal planes. Vast differences are also presented for therapeutic beams at 6-MV and 18-MV x-ray energies. Maximum changes

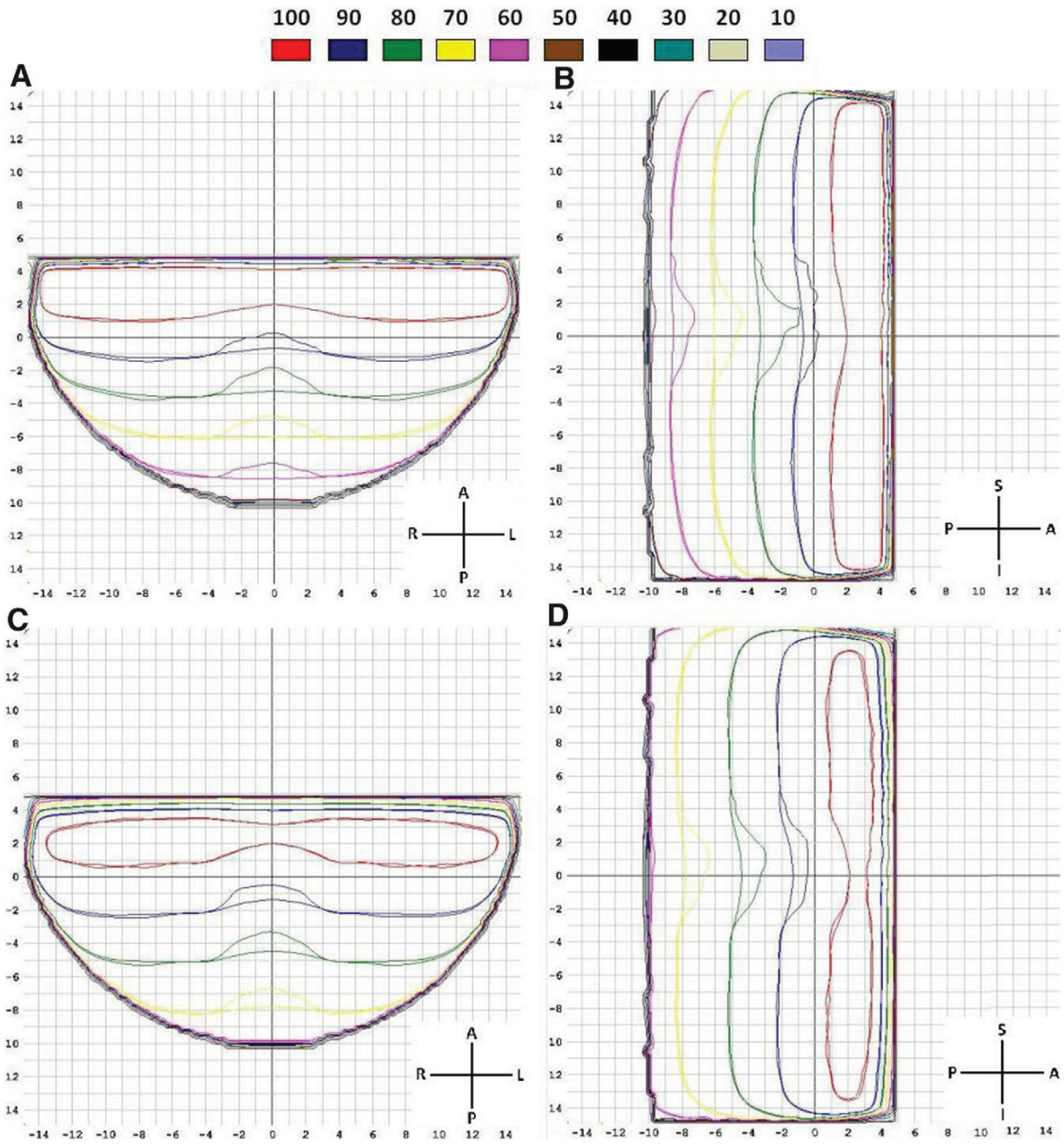

Fig. 2. Beam isodose profiles for the Medtronic, Inc. ICD Concerto model C154DWK (VVE-DDDR) are shown for homogeneous and heterogeneous plan results; (**A**) 6-MV axial plane, (**B**) 6-MV sagittal plane, (**C**) 18-MV axial plane, and (**D**) 18-MV sagittal plane– grid units in cm.

in percentage depth dose are observed for the Medtronic, Inc. ICD Concerto as 9.3% at 6 MV and 10.1% at 18 MV, with worst distance to agreement of isodose lines at 2.3 cm and 1.3 cm, respectively. For the Medtronic, Inc. IP Versa, the maximum changes in percentage depth dose were observed as 10.7% at 6 MV and 6.9% at 18 MV, with worst distance to agreement of isodose lines at 2.5 cm and 1.9 cm, respectively. No differences were marked through dose simulation for the defibrillation leads and the pacing lead.

These findings show evidence of considerable dose change in the beam profile of the medical accelerator. The methods used are novel and vital to the continued care of the patient requiring both cardiovascular care and radiation oncology care. Where >10% variance in the

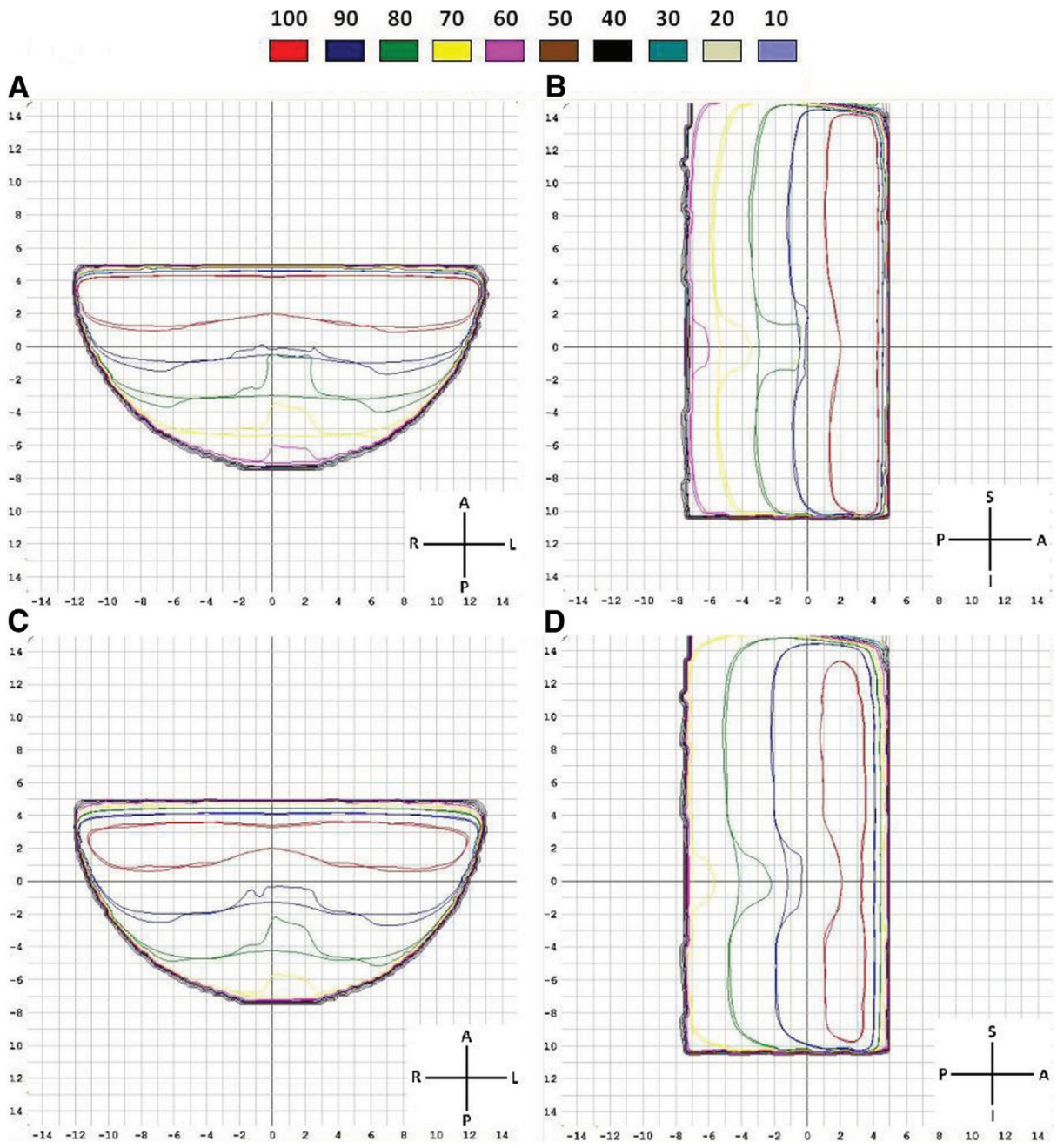

Fig. 3. Beam isodose profiles for the Medtronic, Inc. implantable pacemaker Versa™ model VEDR01 are shown for homogeneous phantom results and heterogeneous results; (**A**) 6 MV axial plane, (**B**) 6 MV sagittal plane, (**C**) 18 MV axial plane, (**D**) 18 MV sagittal plane – grid units in cm.

therapeutic beam profiles is observed, and with depth dose levels shifting by more than 2 cm, assignment of medical accelerator beams to target a disease without an understanding of the full impact these metallic devices have on radiation beams may lead to underdosing the tumor and overdosing normal organs at risk. Avoidance of such medical events may now be possible with the data presented herein.

It is encouraged that radiation oncologists communicate directly with the patient's cardiovascular specialist or electrophysiologist when presented with a patient in whom one or more of these devices has been implanted. The collaborating cardiovascular specialist has the skills necessary to reprogram the device, disable it, and extract or relocate it as deemed necessary. Conversely, it is recommended that the initial placement of implantable

Table 1. Maximum calculations of percentage depth dose change and distance to agreement for planned beam profile distributions involving both cardiac devices at x-ray energies of 6 MV and 18 MV *via* direct comparison of a homogeneous phantom to one with the device embedded

			Axial Plane (L-R lateral)					Sagittal Plane (sup-inf)	
			Maximum	Location				Maximum	Location
ICD	6 MV	Max Δ%DD	5.3%	Center	ICD	6 MV	Max Δ%DD	9.3%	Superior
		DTA at max Δ%DD	1.3 cm				DTA at max Δ%DD	2.3 cm	
	18 MV	Max Δ%DD	3.6%	Center		18 MV	Max Δ%DD	10.1%	Superior
		DTA at max Δ%DD	1.0 cm				DTA at max Δ%DD	1.3 cm	
IP	6 MV	Max Δ%DD	10.0%	Left	IP	6 MV	Max Δ%DD	10.7%	Center
		DTA at max Δ%DD	2.3 cm				DTA at max Δ%DD	2.5 cm	
	18 MV	Max Δ%DD	6.9%	Left		18 MV	Max Δ%DD	6.3%	Center
		DTA at max Δ%DD	1.9 cm				DTA at max Δ%DD	1.8 cm	

stimulating devices be managed with watchful detail of the likelihood for continued care throughout radiation treatment. Medical physicists should present all findings to the radiation oncologist when discovered. They should also assess the treatment planning scheme in accordance to established AAPM guidance on dose limits to the device, as well as direct appraisal of the treatment approach with these data presented. Treatment planning with high-energy x-ray beams involving cardiac devices, such as the Medtronic, Inc. ICD Concerto and the IP Versa without extended HU CT correction and algorithmic heterogeneity density dose calculation is not recommended.

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