Title page

Efficiency of the RADPAD® surgical cap in reducing brain exposure during pacemaker and defibrillator implantation

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Summary for use on social media:

During device implantation the RADPAD® cap decreased the skin front head exposure but had no impact on brain dose distribution as the exposure comes from upwards scattered radiation. #Electrophysiology #RadiationProtection #Brain #ProtectiveCap

Structured abstract

Objectives. Our study investigates the RADPAD® No Brainer® efficiency in reducing brain exposure to scattered radiation.

Background. Cranial radioprotective caps such as the RADPAD® No Brainer® are being marketed as devices that significantly reduce operator's brain exposure to scattered radiation. The efficiency of the RADPAD® No Brainer® in reducing brain exposure in clinical practice remains, however, unknown to date.

Methods. Five electrophysiologists performing device implantations over a two-month period wore the RADPAD® cap with two strips of 11 thermo luminescence dosimeters pellets covering the front head above and under the shielded cap. Phantom measurements and Monte Carlo simulations were performed to further investigate brain dose distribution.

Results. Our study showed that the right half of the operators' front head was the most exposed region during left subpectoral device implantation; the RADPAD® cap attenuated the skin front head exposure, but provided no protection to the brain. The exposure of the anterior part of the brain was decreased by a factor of 4.5 compared to the front head skin value thanks to the skull. The RADPAD® cap worn as a protruding horizontal plane, however, reduced brain exposure by a factor of 1.7 [1.3 ; 1.9].

Conclusion. During device implantation, the RADPAD® No Brainer® decreased the skin front head exposure but had no impact on brain dose distribution. The RADPAD® No Brainer® worn as a horizontal plane worn around the neck reduces brain exposure and confirms that the exposure comes from upwards scattered radiation.

Key words

Electrophysiology, Radiation protection, Brain, Protective cap

Condensed abstract

Clinical measurements, phantom measurements and Monte Carlo simulations were performed to investigate the RADPAD® No Brainer® efficiency in reducing brain exposure to scattered radiation. The RADPAD® No Brainer® worn as a cap decreased the skin front head exposure but had no impact on brain dose distribution.

Abbreviations List

CHUV: Lausanne University Hospital

CRT: Cardiac Resynchronization Therapy

$H_p(0.07)$: Skin Personal Dose Equivalent

$H_p(10)$: Personal Deep Dose Equivalent

ICD: Implantable Cardioverter Defibrillator

IRA: Institute of Radiation Physics

PM: Pacemaker

TLD: Thermo Luminescence Dosimeter

Text

1. Introduction

Several cases of malignant tumors affecting the brain, head or neck have been published over the last decade, with predominantly left-sided lesions for interventionalists practicing with the X-Ray tube on their left side (1). Although a direct link between interventionalists exposure and brain tumor has not been strictly established yet, a recent review has raised concerns about a potential association (1). Cranial radioprotective caps are being marketed as devices that significantly decrease brain exposure during fluoroscopically-guided interventions (2). The RADPAD® No Brainer® is a lead-equivalent surgical cap that supposedly reduces exposure to scattered radiation from 50% to 95% (3). However, data showing any benefit of the efficiency of the RADPAD® No Brainer® on brain exposure are missing. The efficiency of the RADPAD® No Brainer® in reducing brain exposure in real-life conditions such as during pacemaker (PM) and implantable cardioverter defibrillator (ICD) interventions remains unknown to date. Our study is aimed at measuring head and brain electrophysiologists exposure reduction provided by the RADPAD® cap during device implantations using clinical and simulation measurements.

2. Methods

2.1. Materials

2.1.1. Surgical cap

The cap used in this study was the RADPAD® No Brainer® surgical cap with a lead equivalence of 0,25 mm (at 90 kVp), manufactured by Worldwide Innovation & Technologies, inc (Kansas, USA) (3). The cap is a lead free, disposable product.

2.1.2. Dosimeters

This study was conducted using Thermo Luminescence Dosimeters (TLD, LiF: MCP-N, Mg, Cu, P) pellets provided by the dosimetry service of the Institute of Radiation Physics (IRA) of the Lausanne University Hospital (CHUV). All raw data are provided as absorbed dose in water (Gy). A correction factor was applied to evaluate the skin personal dose equivalent $H_p(0.07)$ for an energy of 50 keV to compensate for the energy response of the detector. No correction factor was applied to evaluate brain exposure. In this article TLD measurement data are given with an uncertainty of 4% (k=1). In addition, an electronic personal dosimeter (DMC 3000, Mirion Technologies, France) was used to estimate the effective dose delivered to the medical staff during measurements under controlled conditions (with phantoms). The results are provided as personal deep dose equivalent $H_p(10)$. DMC 3000 measurement data are given with an uncertainty of 10% according to the supplier.

2.1.3. Phantoms

Measurements under controlled conditions were performed using an Alderson RANDO anthropomorphic phantom (model 200, RSD, USA) to represent the implanting physicians standing next to the X-Ray tube. A heart/thorax phantom (model 800, RSD, USA) was used to simulate the patient generating the scattered radiation field on the intervention table.

2.1.4. Monte Carlo simulations

Monte Carlo simulations were performed with the Geant4 toolkit (4) to compute the absorbed dose in the brain received by a physician staying beside a patient lying on a table and irradiated from the bottom by the scattered radiation field (figure 1S - supplemental data) .

In this model the patient is represented by a water cylinder phantom. The physician is represented by the ICRP Male voxel phantom (5). “Without skull” simulations were performed replacing skull voxels by air instead of bone tissue in the ICRP voxel phantom. The center of the head of the ICRP phantom was set at a distance of 97 cm and an angle of 33 degrees from the center axis of the cylinder patient. The 33-degree angle represents the angle between the vertical direction of the X-Ray tube and the direction passing through the patient’s scattering center and the ICRP phantom’s head.

The RADPAD® is represented by three adjacent lead foils, with a thickness of 250 µm and an height of 10 cm surrounding the upper part of the front head. These RADPAD® foils are set along the box-limit of the voxel head phantom.

The X-Ray tube is placed below the couch irradiating from the bottom (vertical direction) directly on the patient water cylinder **with a square field of 20 x 20 cm**; the physician is exposed to scattered radiation coming upwards from the patient. The primary X-Ray spectrum considered in the simulation was generated with an online tool for a peak voltage of 75 kVp (6), with 0.3 mm Cu and 1 mm Al filtration representative of the conditions used in clinical routine. A statistics of 6.10^9 primary X-Rays were generated for each simulation.

2.1.5. Imaging system

The imaging system used is an Axiom Artis dFCMN (Siemens Healthcare, Germany). Clinical measurements were performed in fluoroscopy mode with the following settings: a mean tube tension between 70 and 80 kV (table 1), a current intensity of 155 mA, a square field of 20 x 20 cm and 3 frames per second (fps). Measurements under controlled conditions were performed in the cine mode with the following settings: tube tension 61.5 kV, current intensity ~ 600 mA, square field 20 x 20 cm, 30 fps. The “cine mode” was used to reach a sufficient

cumulative dose level in a reasonable time to minimize dosimeters measurements uncertainties. These data are still transferable to the clinical setting as the cine mode appears to have **a limited** impact on beam quality **in our specific case**.

2.1.6. Statistical analysis

A linear mixed-model with random effects was applied to estimate the mean differences in personal dose equivalent between cap sides (under vs above the cap) at each position around the head. In this model, the electrophysiologists were treated as a random factor, while cap side and position were considered as the fixed predictive factors. This method takes into account the lack of independence of measures repeated within the electrophysiologists. Our interest was in testing the statistical interaction between cap side and position. Its existence would show that the differences between measures under and above the cap vary according to the position around the head. A Wald chi-squared test was applied to test whether the multiple interaction terms in the model were jointly significant. After statistically significant Wald test, model predicted mean cap side differences at each position were estimated together with Bonferroni-corrected 95% confidence intervals to account for multiple testing. The analyses were performed with the statistical package Stata/IC, version 16.0 (StataCorp LLC, College Station, TX, USA). Data are presented as mean values and standard deviation. The attenuation factor provided by the skull (table 1S – supplemental data) was calculated as the ratio of the skin absorbed dose upon the brain absorbed dose including the skull.

2.2. Clinical measurements

Five operators from the Arrhythmia Unit of the service of Cardiology in CHUV participated in this study over a two-month period in order to cumulate enough dose to reach the detection limit of the TLDs to become significant for comparisons. Operators' exposure came from scattered radiations delivered by the patients with the X-Ray tube standing vertically below the table during most of the procedures. Each physician was asked to wear a RADPAD® cap on which two strips of 11 TLD pellets were equally interspaced every 2 cm on the anterior half of the pad covering the front head above and under the shielded material (figure 1A). A shield hanging below the table and placed between the operator and the tube was systematically used during implantations. The measurements were performed without any distinction between the different procedures routinely performed in the unit: permanent PM, ICD or cardiac resynchronization therapy (CRT). This study received formal exemption from the CER-VD (Switzerland) ethics committee, as the project does not collect data from the participants. Table 1 (and table 2S - supplemental data) details for each implanting physician the number of procedures as well as the total fluoroscopy time, the mean voltage and total dose area product, which is used to assess the patient's radiation risk for an interventional procedure. For technical reasons, the mean voltage for implanting physician number 5 was not available.

2.3. Measurements under controlled conditions

The RANDO phantom (figure 1B) representing the implanting physician was equipped with 33 TLDs evenly placed intracranially, a strip of 11 TLD pellets equally distributed every 2 cm on the phantom front head (red arrow) and an operational dosimeter positioned on the phantom chest (green arrow). Two sets of measurements were performed. The first set was completed bareheaded, *i.e.* without the RADPAD® cap, while the second one was performed with a RADPAD® cap protecting both intracranial and front head TLDs. As a second step (figure 1C),

the RANDO phantom with the 33 intracranial TLDs and the operational chest dosimeter was equipped with the RADPAD® protection worn as a protruding horizontal plane. **The objective of the specific set-up with the protective gear worn as a protruding horizontal plane below the chin is to demonstrate that the dose to the brain is due to upwards scattered radiation, but not to propose a new solution to be used in clinical routine**.

3. Results

3.1. Clinical efficiency of the RADPAD® No Brainer® surgical cap

Table 2 and figure 2A report the skin personal dose equivalent $H_p(0.07)$ along the front head of the five operators above (blue) and under (red) the RADPAD® cap. The mixed-model produced a statistically significant interaction between cap sides and position around the head (Wald test: $p<0.001$), indicating that the difference in cumulated dose between cap sides changes according to the position around the head. Model based estimations show under the cap a fairly constant mean cumulated dose from the left to the right temple, while the mean dose increased from the left to the right temple above the cap, being clearly above the under-cap values from position F5 to the right temple (Table 2 and figure 2A). This asymmetric distribution stemmed from the position of the operators standing on the left side of the patients' chest with their right temple directed towards the X-Ray tube. Figure 2B shows that the mean difference between cap sides is almost inexistent from the left temple until position F3, starts increasing from position F4 with a maximum on the front head, and remains high from F7 to the right temple (Table 2, table 2S – supplemental data and figure 2B). All cap side differences between F5 and the right temple bear a statistically significant difference from zero (Table 2, table 2S – supplemental data and figure 2B). The maximum two-month cumulated skin personal dose equivalent $H_p(0.07)$ reached less than 250 μSv (figure 2A, blue line), resulting in a maximum estimated dose of 2 mSv/year to the operator's skin when the head was not protected by the RADPAD® cap.

3.2. Efficiency of the RADPAD® No Brainer® surgical cap evaluated with phantoms

During measurements under controlled conditions, an attenuation factors of 2.3 for skin exposure provided by the RADPAD® cap along the front head was calculated. These measurements (figure 3A, red box) show that the attenuation factors for brain exposure with the RADPAD® cap is close to the unit (1.1 [1.0 ; 1.1], median and interquartile values), hence providing no protection to the brain. There was no correlation between front head skin dose and brain dose as the dose to the brain remained the same regardless of the cumulated personal dose equivalent at the front head skin. Figure 3B reports the absorbed dose distribution into the brain from the vertex (slice 1) to the base (slice 3) of the skull. Note the anteroposterior absorbed dose gradient as shown by higher values in front head TLDs (e.g. TLDs 21) and lower ones for occipital ones (e.g. TLDs 3), which is coherent with the operator's position relative to the X-Ray tube. Similarly, a caudocranial absorbed dose gradient is observed as shown by higher values for basal TLDs and lower ones for vertex TLDs (e.g. TLD 8 and 12). This finding matches with the position of the operator's head standing above the patient. The phantom was then equipped with the RADPAD® No Brainer® protection worn as a protruding horizontal plane. Interestingly, measurements under controlled conditions (figure 3A, green box) show a 1.7 [1.3 ; 1.9] (median and interquartile values) attenuation factor for brain exposure, which is significantly higher than the value for the RADPAD® worn as a cap.

The ratio for the chest personal dose equivalent $H_p(10)$ over the skin personal dose equivalent $H_p(0.07)$ was 1.1 (table 1S – supplemental data), meaning that the chest personal dose equivalent is representative of the front head value measured without any RADPAD® protection. An attenuation factor of 4.5 for the skin absorbed dose at the median front head over the anterior brain absorbed dose (TLD 21) was reported (table 1S – supplemental data). This attenuation factor of 4.5 between the skin front head equivalent dose and the brain equivalent dose just below the bone suggests that the shielding effect is significant and that the skull is

more efficient than the RADPAD® in protecting the brain for direct exposure (an additional protective material should be considered for the exposure from upwards scattered radiation)**.**

3.3. Evaluation of the efficiency of the RADPAD® No Brainer® surgical cap using Monte Carlo simulations

The absorbed dose distribution for a slice of brain (colored map) and the mean absorbed dose in the brain under free conditions are reported **in figure 2S – supplemental data:** panel A, without both the skull and the RADPAD® cap; panel B, with the skull but without the RADPAD® cap; panel C, with both the skull and the RADPAD® cap. As expected, the brain front head exposure (10^{-6} to 10^{-7} pGy/X-Ray) was greater than that of the brain back head (10^{-7} to 10^{-9} pGy/X-Ray) with and without the skull and RADPAD® cap. Note the lower exposition values of the brain provided by the skull (panels B [**7,23**.10^{-8} pGy/X-Ray] and C [**7,10**.10^{-8} pGy/X-Ray] vs A [**1,35**.10^{-7} pGy/X-Ray]) and the lack of protective effect of the RADPAD® as shown by similar exposure distribution between panels B (without) and C (with the RADPAD® cap). Taken together, these simulations suggest that an efficient shielding against radiation is provided to the brain by the skull, but not by the RADPAD® worn as a cap.

4. Discussion

This prospective study encompasses several observations and new findings for electrophysiologists performing device implantations summarized as follow: the right half of the front head's physician is the most exposed region for device implantation performed at the patients' left subpectoral region; the RADPAD® cap attenuates the skin front head exposure, but provides no protection to the brain; the exposure of the anterior part of the brain is decreased

by a factor of 4.5 compared to the front head skin value thanks to the skull; the RADPAD® cap worn as a protruding horizontal plane decreases brain exposure by a factor of 1.7.

4.1. Clinical efficiency of the RADPAD® No Brainer® surgical cap

Several studies on the efficiency of radiation protection surgical caps were published over the past few years (7). The first studied lead cap (0.5 mm lead equivalent) was quite heavy (1140 g) and wrapped the head and neck, with an opening for the eyes, nose and mouth (8,9). Both studies reported a significant attenuation of the head exposure compared to the control conditions mostly for interventionalists performing coronary angiography from the patients' right groin. More recent studies evaluated the efficiency of two models of lightweight lead-free caps worn as a front head band: XPF® caps (1,10,11) and RADPAD® No Brainer® surgical caps (2,12,13). Importantly, the lead equivalence of the studied caps were different (0.06 mm (2), 0.125 mm (12), 0.25 mm (13), 0.3 mm (11), 0.5 mm (1,10,11)). In four publications, the efficiency of the cap was evaluated by placing dosimeters at a single position on the left temporal front head (2,10,11,12). Two studies assessed the efficiency of the cap with a limited number of dosimeters placed at two (13) or three (1) positions on the front head. Although the number of screened positions was limited, the exposure of the front head portion turned toward the X-Ray tube was the highest (1,13). As far as we know, our study is the first that monitored the skin personal dose equivalent $H_p(0.07)$ of the full front head from the right to the left temple, placing dosimeters at 11 positions. Here, in contrast to studies where interventionalists performed neurovascular or coronary procedures (1,2,10,11,12,13) from the right femoral side of the patients, the implanting electrophysiologists stood at the left subpectoral region very close from the X-Ray tube. Our results showed that the right side of the head has a significantly higher exposure (factor of 2.4, figure 2A) than the left one, which is in agreement with former conclusions (1,13).

In five publications, the efficiency of the protection devices was evaluated by placing dosimeters above and under the cap (1,2,10,11,12). The dose measured under the cap was significantly lower than that measured above on the most exposed side. Our results are in agreement with these findings as the skin personal dose equivalent $H_p(0.07)$ measured under the RADPAD® cap was significantly lower than that measured above at seven locations on the most exposed side (table 2). Sans Merce et al. (13) recently reported the lack of significant impact of the cap on the dose measured on the head, even on the most exposed side, which contradicts our observations and those from the literature (1,2,10,11,12). Differences in methodology may explain these contradictory results: first, their measurements were sequentially performed with the dosimeter covered by the RADPAD® cap only during the second period, and, second, with a biplane imaging system. In summary, the RADPAD® cap reduces the skin exposure of the most exposed side of the front head. Note that the maximum dose to the operator's skin upon the RADPAD® cap was estimated to be 2 mSv/year, which is far below the skin limit of 500 mSv/year fixed by the Swiss Radiological Protection Ordinance (14, 15).

4.2. Efficiency of the RADPAD® No Brainer® surgical cap evaluated with phantoms

Kirkwood et al. (2) studied the efficiency of the RADPAD® cap (0.06 mm lead equivalent) using an anthropomorphic head phantom. First, the consistency between the phantom study and the clinical data was assessed by placing a dosimeter on the phantom head surface at the left temporal position, with and without the cap. These results were compared to the data measured under and above the cap at the left temporal location of the surgeon's head. A similar attenuation in the range of 60 to 70% was found in both studies. Using the same measurement method but with TLDs all along the front head surface, our phantom measurements showed a median attenuation factor of 2.3 for skin exposure, consistent with our clinical data showing a 2.2

median attenuation factor along the front head as provided by the cap. Second, these authors (2) reported that the RADPAD® cap provided no significant dose decline at the midbrain level and minimal dose decline at the upper brain level. Our findings are in agreement with their results as the attenuation factor for brain exposure provided by the RADPAD® cap was negligible (1.1), meaning that the brain exposure was the same whether the cap was worn or not. In addition, the attenuation factor for skin exposure (2.3) was twice that for brain exposure (1.1). Our study supports Kirkwood et al.'s (2) conclusion by showing that the attenuation measured on the surface of the head does not reflect the efficiency of the cap in reducing brain exposure. Third, Kirkwood et al. (2) claimed that brain exposure originates from the lower head and neck, which are regions not protected by the cap. As far as we know, our study is the first where phantom measurements assessed the dose distribution inside the brain (figure 3B). Our results revealed a caudocranial absorbed dose gradient that support previous findings (2). In addition, our phantom measurements were performed with the RADPAD® worn as a protruding horizontal plane to protect lower head and neck region (figure 1C). A median attenuation factor for brain exposure of 1.7 was found that was significantly higher than that measured when worn as a cap (figure 3A). **In summary these findings demonstrate that the dose to the brain results from upwards scattered radiation delivered by the patient that do not pass through the cap, while the RADPAD® worn as a protruding horizontal plane significantly reduced brain exposure**.

4.3. Evaluation of the efficiency of the RADPAD® No Brainer® surgical cap using Monte Carlo simulations

Our clinical and phantom measurements found that the RADPAD® worn as a cap reduces skin but not brain exposure. Marsh RM et al. (16) recently estimated that approximately 40% of the scattered radiations are absorbed by the skull and never reach the brain. We therefore

hypothesized that the protective effect of the skull overcomes the RADPAD® cap efficiency in reducing brain exposure. In our phantom measurements, a 4.5 attenuation factor was provided by the skull for two nearby anterior positions above and under the cranium. Monte Carlo simulations were performed to provide a direct comparison between a normal head and a fictive situation without the skull (figure **2S – supplemental data**). The data indicate that the skull provides such a protection that the RADPAD® worn as a cap yields a marginal benefit. In summary, the skull appears as an efficient shielding for the brain but the RADPAD® worn as a cap provides marginal protection.

4.4. Limitations

The following limitations can be acknowledged.

First, clinical measurements were performed without any distinction between the different procedures routinely performed in the unit. The aim was to get enough dose on the dosimeters at the end of the measurement period (compared to the detection limit of the dosimeters). The detection limit of the dosimeters couldn't be reached by measuring the dose for each procedure type separately. Second, the impact of operator's height has not been tested. The scope of this paper is aimed at investigating the efficiency of the protective cap under representative routine workload, where the potential impact of each operator's morphological parameter has not been considered. Third, measurements under controlled conditions have only been performed with the tube in a vertical position, while the clinical measurements included several tube angulations left to the discretion of the operators. These experimental measurements were also performed in cine mode assuming that these data are still transferable to the clinical setting as they have minor impact on beam quality. The tube voltage (kVp) in cine mode, however, are 10% lower than the voltage used in fluoroscopy mode. This difference in mean beam energy (~ 8 keV) in the primary beam is considered negligible on the characteristics of the scattered radiation field.

Fourth, in our Monte Carlo simulations, the RADPAD® is represented by three adjacent lead foils, whereas the RADPAD® No Brainer® is actually composed of an alloy of tin and bismuth. Precautions have be taken with regards to the thickness of lead foils (250 µm), so that it corresponds to the lead-equivalent thickness of the protective material of the RADPAD® No Brainer® for the tube tension used by the staff during the procedures (Pb-eq thickness of 0.25mm at 90kVp). Fifth, similar results were surprisingly found for 0.06 mm and 0.25 mm lead equivalent RADPAD® caps, which is suggestive of a contribution from internal scattered radiation. Future research beyond the scope of the present manuscript should evaluate the contribution of the internal scattering as a function of the type of procedures (kVp, tube position and angle) and the type of protective gears used during procedures (both collective and personal). Finally, the objective of the specific set-up with the protective gear worn as a protruding horizontal plane below the chin was to demonstrate that the dose to the brain is due to upwards scattered radiation, but not to propose a new solution to be used in clinical routine. Our results suggest that the lack of efficiency of the RADPAD® worn as a cap does not come from the RADPAD® gear itself but from its position on the front head. Future research beyond the scope of the present manuscript should compare the efficiency of the RADPAD® worn as a protruding horizontal plane to existing radiation protection options (Zero Gravity, RADPAD® drape, etc.) placed directly between operators and the scattered X-Ray source.

4.5. Conclusion

This study shows that the right half of the front head's physician is the most exposed region for device implantation performed at the patients' left subpectoral region. The RADPAD® No Brainer® worn as a cap did not provide protection to the brain because of upward scattered

radiation coming from the patient. The same gear worn as a protruding horizontal plane below the chin reduced brain exposure by a factor of 1.7.

Clinical Perspectives

The right half of the front head's physician is the most exposed region for device implantation performed at the patients' left subpectoral region. The RADPAD® cap attenuates the skin front head exposure, but provides no protection to the brain. The exposure of the anterior part of the brain is decreased by a factor of 4.5 compared to the front head skin value thanks to the skull. The RADPAD® cap worn as a protruding horizontal plane does reduce brain exposure by a factor of 1.7.

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Figure titles and legends

Figure 1. Material. (A) RADPAD® cap equipped with TLDs distributed along the phantom front head. (B) Upper left: TLDs placed inside the phantom brain. Upper right: TLDs along the front head (red arrow) with operational dosimeter on the chest (green arrow). X-Ray exposure of the phantom without (lower left) and with (lower right) the RADPAD® cap. (C) RADPAD® cap **worn as a protruding horizontal plane. X-Ray** exposure of the phantom with TLDs placed in the brain (red arrow) and operational dosimeter placed on the chest (green arrow).

Figure 2. Evaluation of the efficiency of the RADPAD® No Brainer® surgical cap using clinical measurements. (A) Model estimated mean two-month cumulated personal dose equivalent $H_p(0.07)$ along the front head above and under the RADPAD® cap for each position, with 95% confidence intervals. (B) Model estimated mean differences with Bonferroni-corrected 95% confidence intervals.

Figure 3. Evaluation of the efficiency of the RADPAD® No Brainer® surgical cap using phantoms measurements. (A) Red: Attenuation factor for brain exposure with the RADPAD® No Brainer® protection worn as a front head cap. Green: Attenuation factor for brain exposure with the RADPAD® No Brainer® protection worn as a protruding horizontal plane. (B) Absorbed dose distribution in the brain from the vertex (slice 1) to the base (slice 3) of the skull.

Tables

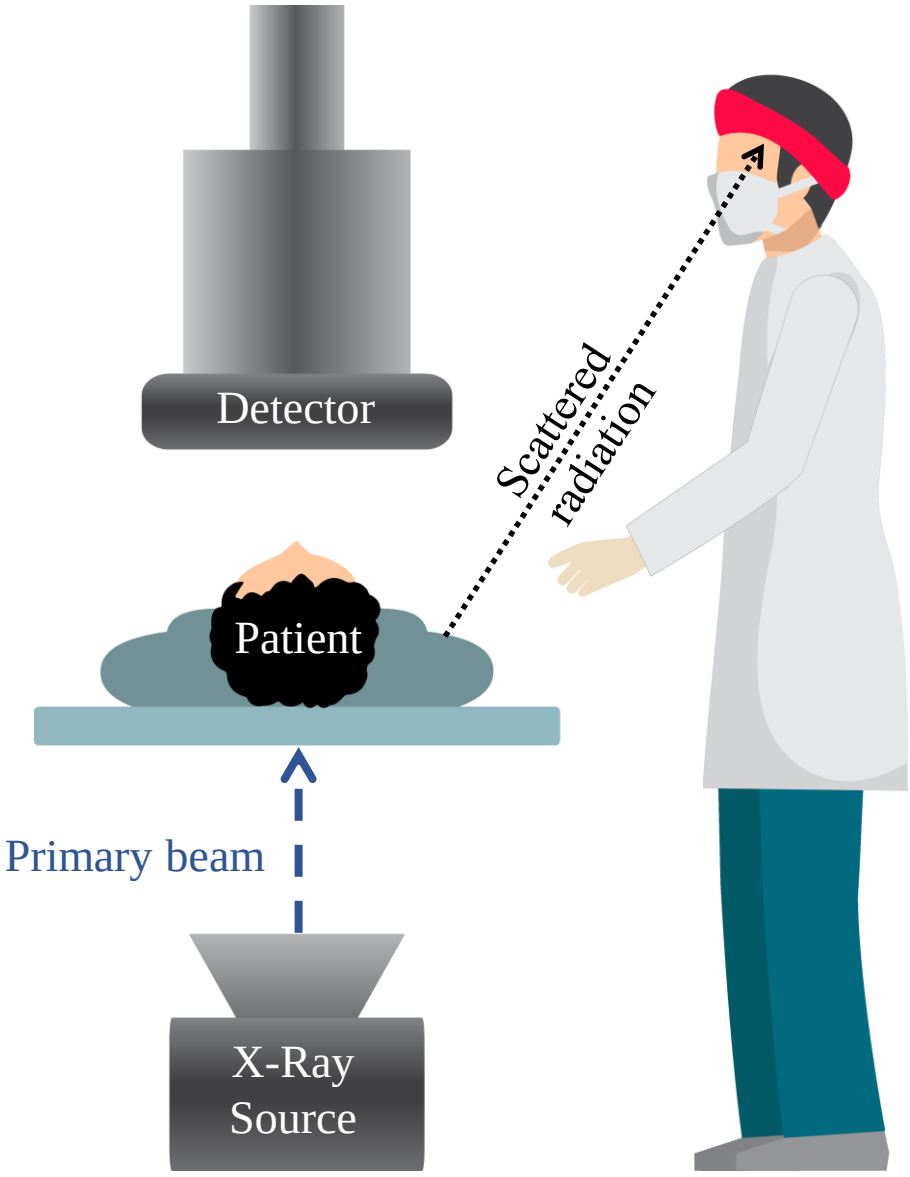
Table 1. Procedures and X-Ray data per implanting physician

	Number of procedures	Cumulative fluoro time (min)	Mean tube tension (kV)	Total dose area product ($cGycm^2$)
Op 1	15	60.25	70.23	8089.00
Op 2	13	87.03	72.39	8940.90
Op 3	15	171.45	71.82	22328.10
Op 4	5	146.19	78.30	28558.50
Op 5	39	203.67	-	42031.20

Table 2. Model estimated mean two-month cumulated personal dose equivalent $H_p(0.07)$ above and under the cap for each position.

	F1 Left temple	**F2**	**F3**	**F4**	**F5**	**F6 Front head**	**F7**	**F8**	**F9**	**F10**	**F11 Right temple**
Mean cumulated dose above the cap [µSv]	47.6	49.3	61.3	90.7	133.7	165.4	140.3	133.5	145.4	162.7	175.4
Standard deviation	16.7	16.7	16.8	17.1	17.6	18.1	18.8	19.6	20.5	21.5	22.6
Mean cumulated dose under the cap [µSv]	41.1	46.1	50.1	51.8	64.2	46.9	52.0	41.7	51.3	54.8	72.4
Standard deviation	12.3	12.4	12.7	13.3	14.0	14.8	15.8	16.9	18.0	19.2	20.5
Bonferroni p-value	1.000	1.000	1.000	0.573	0.006	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

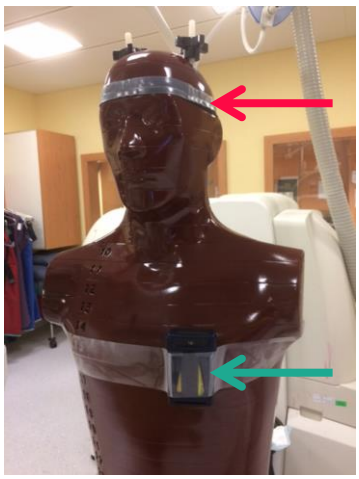
P-values for the estimated mean differences are Bonferroni-corrected.



Scattered radiation reaches the operator's head from below, preventing any efficiency of the RADPAD® worn as a cap in reducing brain exposure.

A

B



C

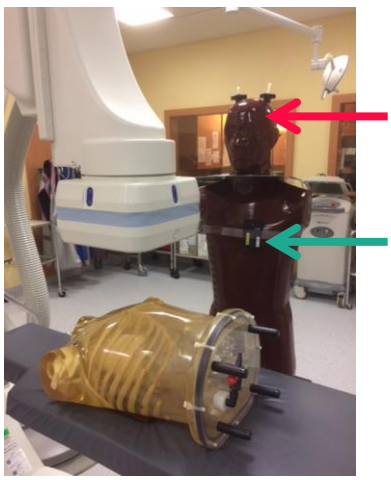
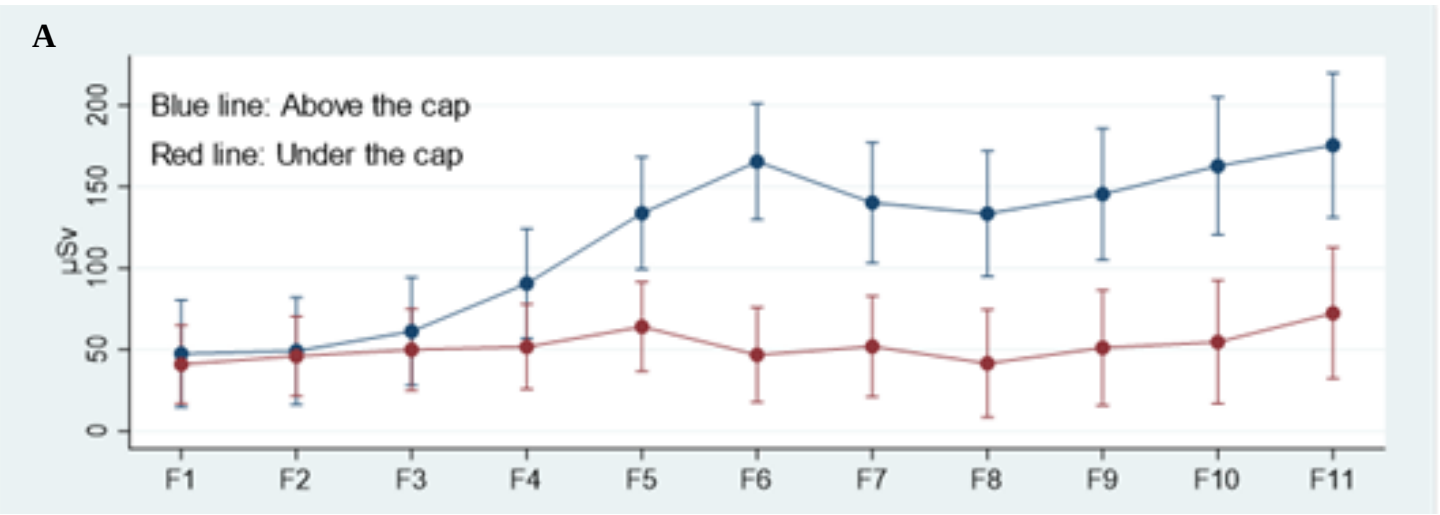


Figure 1


A
Blue line: Above the cap
Red line: Under the cap
µSv
0
50
100
150
200
F1
F2
F3
F4
F5
F6
F7
F8
F9
F10
F11

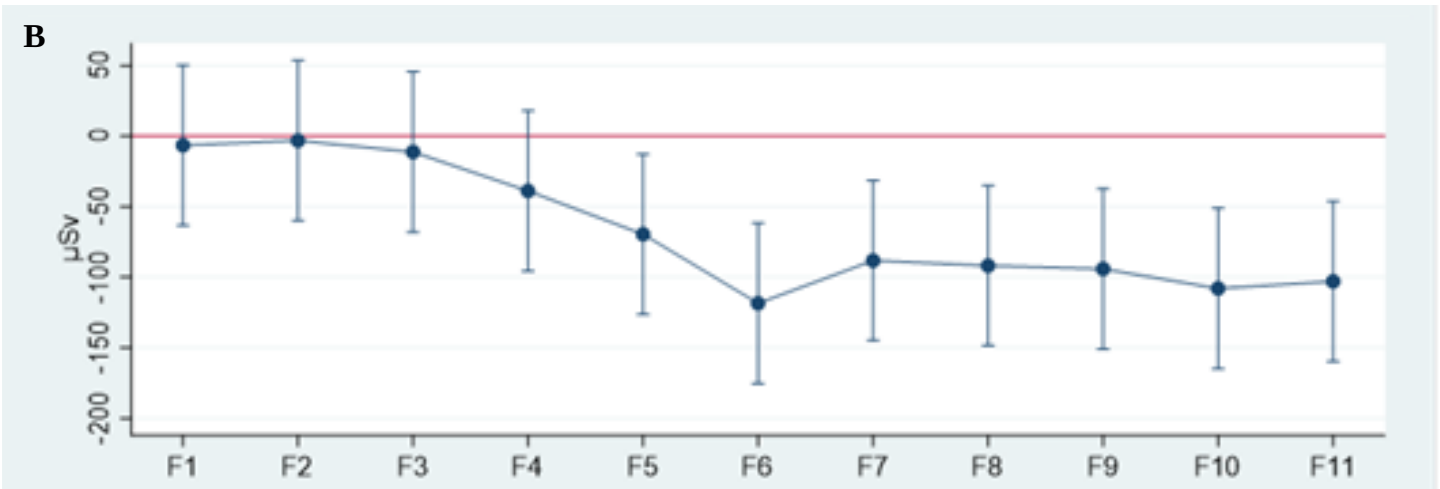

B
µSv
50
0
-50
-100
-150
-200
F1
F2
F3
F4
F5
F6
F7
F8
F9
F10
F11

Figure 2

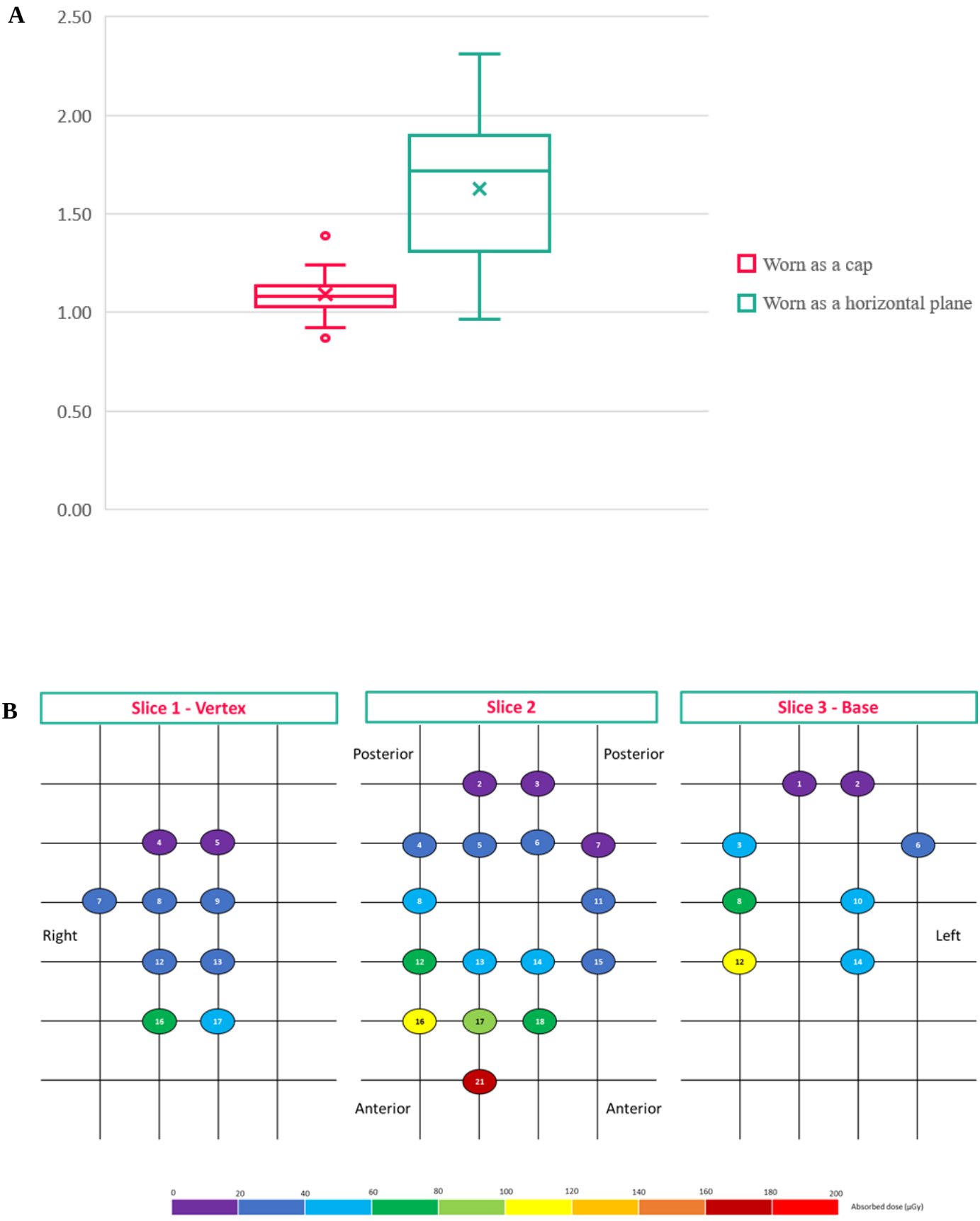
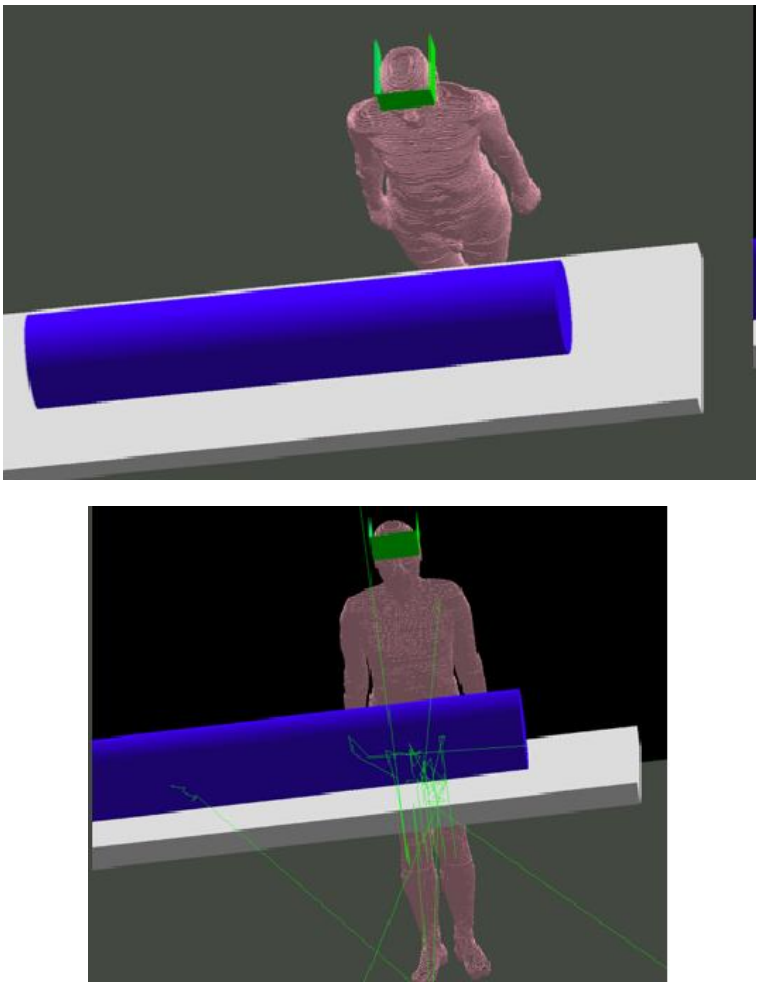

A
2.50
2.00
1.50
1.00
0.50
0.00
Worn as a cap
Worn as a horizontal plane
B
Slice 1 - Vertex
Slice 2
Slice 3 - Base
Posterior
Posterior
Right
Left
Anterior
Anterior
0
20
40
60
80
100
120
140
160
180
200
Absorbed dose (µGy)

Figure 3

A



B

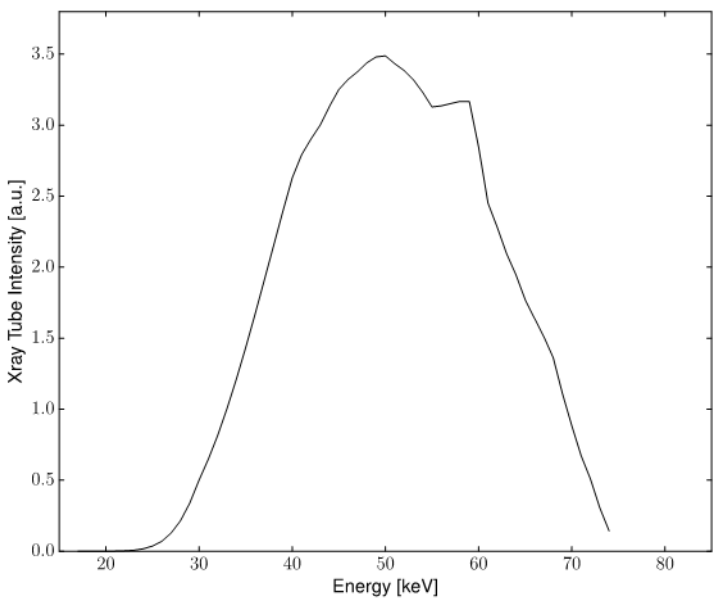


Figure 1S - supplemental data

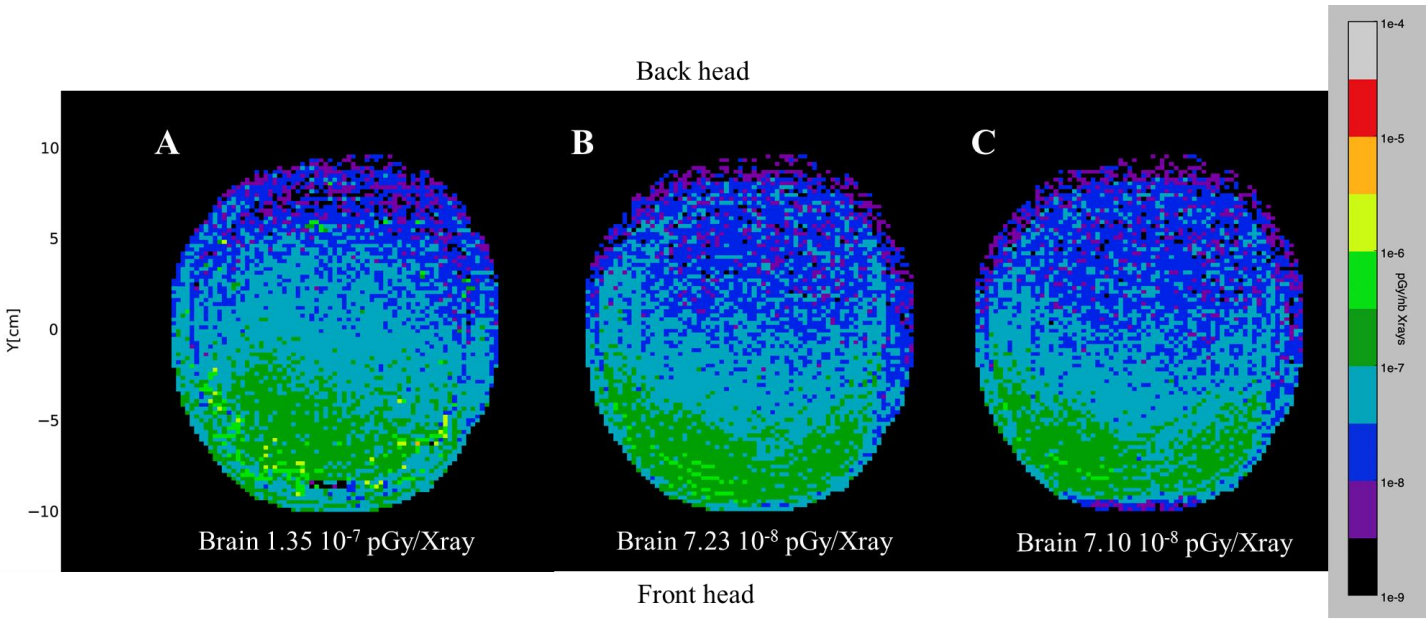


Figure 2S – supplemental data

Supplemental data

Supplemental figures titles and legends

Figure 1S. Monte Carlo simulations. (A) Visualization of the geometrical model used in the GEANT4 Monte Carlo simulations for the shielding capability of the RADPAD. (B) X-Ray spectrum considered in the GEANT4 Monte Carlo simulations.

Figure 2S. Evaluation of the efficiency of the RADPAD® No Brainer® surgical cap using Monte Carlo simulations. (A) Absorbed dose distribution in the brain without both the skull and the RADPAD® cap, (B) with the skull but without the RADPAD® cap, (C) with both the skull and the RADPAD® cap.

Supplemental tables

Table 1S – Supplemental data. Correction factor from chest to skin dose and attenuation factor provided by the skull

		Dose
Chest personal dose equivalent Hp(10) [µSv]		872
Skin personal dose equivalent Hp(0.07) [µSv]		799
Correction factor	1.1	
Skin absorbed dose [µGy]		747
Brain absorbed dose – position 21 [µGy]		167
Attenuation factor provided by the skull	4.5	

Table 2S - supplemental data. Details of the implanted devices with respective fluoroscopy time and dose area product

	Single and double chamber pacemakers			Single and double chamber implantable cardioverter defibrillator			Cardiac resynchronization therapy pacemaker and defibrillator		
	Number	Mean fluoro time (min)	Mean dose area product (cGycm2)	Number	Mean fluoro time (min)	Mean dose area product (cGycm2)	Number	Mean fluoro time (min)	Mean dose area product (cGycm2)
Op 1	10	4.78	661.71	5	3.67	431.58	0	-	-
Op 2	10	6.51	716.63	2	5.11	875.80	1	11.75	742.70
Op 3	9	1.92	368.47	0	-	-	6	25.70	3168.65
Op 4	1	1.80	223.90	0	-	-	4	36.10	7083.65
Mean		4.40	577.45		4.08	558.50		28.21	4371.75
Standard deviation		3.38	484.60		3.14	568.24		19.80	3685.64

Table 3S – Supplemental data. Model estimated mean difference of two-month cumulated personal dose equivalent $H_p(0.07)$ above and under the cap for each position, with 95% confidence intervals.

	F1 Left temple	**F2**	**F3**	**F4**	**F5**	**F6 Front head**	**F7**	**F8**	**F9**	**F10**	**F11 Right temple**
Mean difference	-6.5	- 3.2	- 11.2	- 38.9	- 69.6	- 118.5	- 88.2	- 91.8	- 94.1	- 107.9	- 103.0
Bonferroni 95% CI	- 63.3, 50,3	- 59.9, 53.6	- 68.0, 45.5	- 95.6, 17.9	- 126.3, - 12.8	- 175.3, - 61.8	- 145.0, - 31.5	- 148.6, - 35.1	- 150.9, - 37.4	- 164.7, - 51.2	- 159.7, - 46.2

The 95% confidence intervals are Bonferroni-corrected.