Original paper

A novel perineal shield for low-dose-rate prostate brachytherapy

Joseph P. Weiner, MD[1,2], David Schwartz, MD[1,2], Joseph Safdieh, MD[1,2], Alex Polubarov, CMD[1], Tejas Telivala, MS, DABR[1], Matthew Worth, MS, DABR[1], David Schreiber, MD[1,2]

[1]Department of Radiation Oncology, Veterans Affairs NY Harbor Healthcare System, Brooklyn, New York, [2]Department of Radiation Oncology, SUNY Downstate Medical Center, Brooklyn, New York, USA

Abstract

Purpose: To study the impact on radiation exposure to staff through the use of an original perineal shield during low-dose-rate prostate brachytherapy.

Material and methods: We designed a 1 mm thick stainless steel shield that duplicates and is able to slide directly over a standard commercialized prostate brachytherapy grid. We then analyzed the post-procedure exposure in 15 consecutive patients who underwent Iodine-125 seed placement. Measurements were performed with and without the shield in place at fixed locations relative to the grid template. Endpoints were analyzed using the paired two-sample *t*-test, with statistical significance defined as a *p*-value < 0.05.

Results: The exposure at the midline grid template ranged from 0.144-0.768 mSv/hr without the shield, and 0.038-0.144 mSv/hr with the shield ($p < 0.0001$). The exposure 10 cm left of the grid template was 0.134-0.576 mSv/hr without the shield, and 0.001-0.012 mSv/hr with the shield ($p < 0.0001$). The exposure 10 cm right of the grid template was 0.125-0.576 mSv/hr without the shield, and 0.001-0.012 mSv/hr with the shield ($p < 0.0001$). The median reduction of exposure at the grid was 76% midline, 98.5% left, and 99% right. Similarly, each individual dose rate was recorded at 25 cm from the perineum, both with and without shield. The median reduction of exposure 25 cm from the perineum was 73.7% midline, 77.7% left and 81.6% right ($p < 0.0001$).

Conclusions: Our novel shield took seconds to install and was non-restrictive during the procedure, and provided at least a four-fold reduction in radiation exposure to the brachytherapist.

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Purpose

Prostate cancer remains the most common non-cutaneous malignancy diagnosed in the United States, with an estimated 220 800 new diagnoses and 27 540 deaths expected in 2015 [1]. Over 80% of these men will present with localized, curative disease, for which the 5-year relative survival rate approaches 100% [2]. Men with a high probability of organ-confined disease can be offered brachytherapy as monotherapy, while men with a significant risk of extraprostatic extension can be offered brachytherapy with supplemental external beam radiation therapy [3-5].

It is estimated that as many as 50 000 men are treated with interstitial brachytherapy in the United States per year with the vast majority of these implants utilizing low-dose-rate (LDR) [6]. Additionally, patterns of care studies suggest increasing prostate brachytherapy use in Europe as well [7]. A recent survey of current clinical practice in prostate brachytherapy revealed that the mean number of LDR implants per year per brachytherapist was 39, but the range extended up to 200 implants [6]. Despite advances from earlier techniques of prostate brachytherapy, the use of LDR poses inherent risks to both the practitioner performing the implant as well as those in close proximity of the patient [8]. This risk to the practitioner is exacerbated by the lack of mechanized after-loading, which has been employed in high-dose rate (HDR) brachytherapy [9]. Numerous articles reporting data about radiation exposure to the general public exist [10-12]. In addition, the literature also includes practical and effective methods of reducing exposure to the general public. Such examples of this include minimizing time of exposure and increasing distance to the patient's pelvis [13,14]. Additional examples include dedicated shielding in the form of lead-lined underwear [15,16].

In contrast, less data is available about radiation exposure to personnel performing the implant [17]. When such information is discussed in the literature, it is usually limited and involves one site of interest, such as the eye

Address for correspondence: Joseph P. Weiner, MD, Department of Radiation Oncology, SUNY Downstate Medical Center, 450 Clarkson Avenue, Brooklyn, NY 11203, USA, phone: +1 718 270-1593, fax: +1 718 270-1535, ✉ e-mail: Joseph.Weiner@downstate.edu

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or hand [18,19]. Despite this, even fewer articles discuss techniques or materials that can help reduce exposure to the medical staff performing the implant. In this study, we analyzed the results of our newly created brachytherapy shield that has minimal to no impact on the set-up time or the ability to perform the brachytherapy procedure but is able to significantly reduce radiation exposure.

Material and methods

Shield design

A novel shield model system was constructed to enable sufficient dose reduction to medical personal (Fig. 1). The overall design of the system was a 1 mm thick stainless steel shield with duplicate holes and markings to a standard, commercially available prostate brachytherapy grid (Civco Medical Solutions, Disposable Template Grid, Orange City, Iowa, USA). Stainless steel was chosen for shield as this material provides significant attenuation of the radiation and is also able to safely undergo autoclaving after use, allowing for repeated use of the shield. The thickness of 1 mm was similarly chosen in order to provide radiation shielding with the minimal width shield, in order to make the shield as lightweight and unobtrusive to the procedure as possible. The shield was designed to be taller and wider in dimensions than the grid (21 cm by 21 cm in size) and was constructed to be compatible with our ultrasound stepper system (Civco Medical Solutions, Classic Stepper) but easily adaptable to other systems.

Two stainless steel latches on the back of the shield allows it to slide over the grid and lock into place. Once in place, the openings of the shield and the grid are aligned flush against one another. Therefore, the brachytherapist is able to easily insert the needles through both the shield and grid openings, directly into the perineum. During the procedure, the device is easily installed within seconds

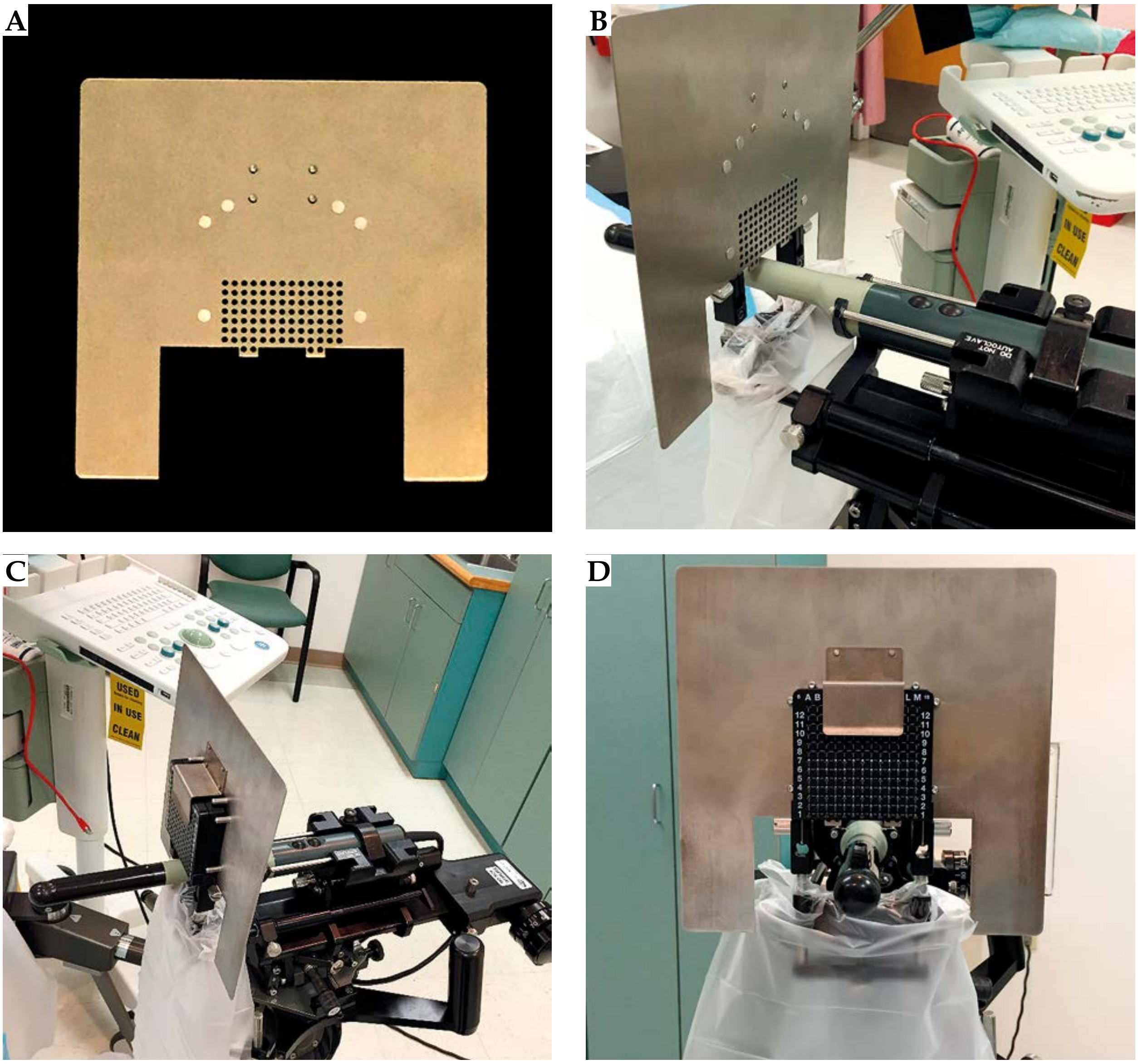

Fig. 1A-D. A) Perineal shield: **B)** oblique anterior view, **C)** oblique posterior view, **D)** posterior view and remains in place for the entire duration of the implant. At the conclusion of the procedure, the device is removed and sent to our sterile processing department where it undergoes steam autoclave prior to use in the next case.

Exposure analysis

We analyzed the post-procedure exposure in 15 consecutive patients who underwent permanent LDR Iodine-125 seed placement for prostate cancer from October 2013 to January 2014. Measurements were performed utilizing a Ludlum Model 14C S/N 80047 air ionization chamber survey meter calibrated yearly against Iodine-125, both with and without the shield in place. Measurement locations were at the grid template, which is flush to the perineum, and at the stepper dial, which was 25 cm from the perineum. At both of these locations, three measurements were taken at the midline, left lateral, and right lateral. At the grid, the lateral measurements were 10 cm off central axis, and at the stepper dial, the lateral measurements were 25 cm off central axis. Endpoints were analyzed using the paired two-sample *t*-test with statistical significance defined as a *p*-value < 0.05.

Results

The prescription dose, individual seed activity, number of seeds, and total implant activity were recorded for each patient (Table 1). Each individual dose rate for all patients at the grid, both with and without shield, was recorded (Table 2). The exposure at the midline grid tem-

Table 1. Patient and seed data

Patient	Rx (Gy)	Activity (mCi)	No seeds	Total activity (mCi)
1	108	0.47	55	25.85
2	108	0.47	41	19.27
3	108	0.47	38	17.86
4	108	0.434	39	16.926
5	108	0.475	34	16.15
6	108	0.512	57	29.184
7	108	0.481	40	19.24
8	108	0.471	57	26.847
9	108	0.461	40	18.44
10	108	0.47	47	22.09
11	108	0.402	42	16.884
12	108	0.47	43	20.21
13	108	0.475	37	17.575
14	108	0.475	54	25.65
15	108	0.47	38	17.86
Mean	108	0.467	44.1	20.67

Table 2. Dose rate in mSv/hr at the template grid

Patient	At central grid		% Reduction	10 cm left of midline		% Reduction	10 cm right of midline		% Reduction
	Shield	No shield		Shield	No shield		Shield	No shield	
1	0.096	0.432	77.8	0.010	0.384	97.4	0.010	0.336	97.0
2	0.144	0.384	62.5	0.007	0.384	98.2	0.004	0.288	98.6
3	0.048	0.144	66.7	0.002	0.134	98.5	0.001	0.125	99.2
4	0.096	0.288	66.7	0.005	0.288	98.3	0.005	0.288	98.3
5	0.144	0.576	75.0	0.004	0.480	99.2	0.004	0.480	99.2
6	0.067	0.288	76.7	0.004	0.240	98.3	0.002	0.192	99.0
7	0.048	0.144	66.7	0.002	0.134	98.5	0.002	0.134	98.5
8	0.048	0.192	75.0	0.002	0.173	98.8	0.001	0.192	99.5
9	0.096	0.384	75.0	0.003	0.336	99.1	0.003	0.336	99.1
10	0.115	0.480	76.0	0.012	0.384	96.9	0.012	0.384	96.9
11	0.038	0.192	80.2	0.002	0.144	98.6	0.001	0.144	99.3
12	0.067	0.384	82.6	0.001	0.240	99.6	0.001	0.240	99.6
13	0.058	0.768	92.4	0.005	0.576	99.1	0.005	0.576	99.1
14	0.067	0.576	88.4	0.005	0.384	98.7	0.005	0.384	98.7
15	0.016	0.192	91.7	0.004	0.144	97.2	0.004	0.144	97.2
Mean	0.077	0.362	76.9	0.004	0.295	98.4	0.004	0.283	98.6

plate ranged from 0.144-0.768 mSv/hr without the shield, and 0.038-0.144 mSv/hr with the shield ($p < 0.0001$). The exposure 10 cm left of the grid template was 0.134-0.576 mSv/hr without the shield, and 0.001-0.012 mSv/hr with the shield ($p < 0.0001$). The exposure 10 cm right of the grid template was 0.125-0.576 mSv/hr without the shield, and 0.001-0.012 mSv/hr with the shield ($p < 0.0001$). The median reduction of exposure at the grid was 76% midline, 98.5% left and 99% right.

Each individual dose rate for all patients at the stepper dial, located 25 cm from the perineum, both with and without shield, was also recorded (Table 3). The exposure at the midline, 25 cm from the perineum, ranged from 0.013-0.058 mSv/hr without the shield, and 0.004-0.019 mSv/hr with the shield ($p < 0.0001$). The exposure 25 cm from the perineum and left of midline was 0.013-0.058 mSv/hr without the shield, and 0.002-0.012 mSv/hr with the shield ($p < 0.0001$). The exposure 25 cm from the perineum and right of midline was 0.013-0.048 mSv/hr without the shield, and 0.002-0.012mSv/hr with the shield ($p < 0.0001$). The median reduction of exposure 25 cm from the perineum was 73.7% midline, 77.7% left, and 81.6% right.

Discussion

Principles of radiation safety during brachytherapy implantation include limiting time of exposure, increasing distance from the source, avoiding unnecessary exposure and shielding with protective materials. While in the clinical setting, the first three concepts may be challenging to quickly enact meaningful change, the latter-most idea of shielding can be implemented without significant cost or time commitment. The benefit of the perineal shield presented in this paper is a four-fold reduction in radiation exposure to the brachytherapist. This device takes seconds to install and is non-restrictive during the procedure.

A review of the existing literature reveals no previously described perineal shield designed with the purpose of protecting staff during brachytherapy implant. Most existing radiation safety literature describes exposure with respect to the community or family of the patient rather than the practitioner [11,12]. One such study investigating dose to the performing staff determined that with the use of personal lead, body doses were near negligible but hands received the highest doses, an average of 420 microSv per implant [20]. Recently, another study described post-implant surface dose after brachytherapy with and without the use of 0.1 mm thickness lead-lined underwear [15]. The magnitude of radiation exposure attenuation was > 90%, and confirmed that such shielding is effective in the post-brachytherapy setting to reduce exposure to the community. These two studies, though with different purposes, exemplify the ability of shielding to reduce exposure.

In our study we found that the perineal shield reduced the radiation exposure by a median of 76% at the grid and 98-99% lateral to the grid. However, prior studies of the attenuation of stainless steel for Iodine 125 have revealed that 1 mm of stainless steel should reduce exposure by

Table 3. Dose rate in mSv/hr at stepper dial (25 cm from perineum)

Patient	At central		% Reduction	25 cm left of midline		% Reduction	25 cm right of midline		% Reduction
	Shield	No shield		Shield	No shield		Shield	No shield	
1	0.019	0.048	60.4	0.008	0.058	86.2	0.008	0.058	86.2
2	0.013	0.048	72.9	0.012	0.038	68.4	0.012	0.038	68.4
3	0.012	0.058	79.4	NA	NA	NA	NA	NA	NA
4	0.010	0.038	73.7	0.012	0.038	68.4	0.012	0.038	68.4
5	0.011	0.038	71.1	0.010	0.038	73.7	0.010	0.038	73.7
6	0.010	0.038	73.7	0.007	0.029	75.9	0.007	0.038	81.6
7	0.005	0.019	73.7	0.004	0.024	83.3	0.004	0.024	83.3
8	0.005	0.019	73.7	0.003	0.019	84.2	0.003	0.019	84.2
9	0.012	0.038	68.4	0.007	0.038	81.6	0.007	0.038	81.6
10	0.005	0.029	82.8	0.009	0.038	76.3	0.007	0.038	81.6
11	0.005	0.014	64.3	0.004	0.012	66.7	0.004	0.014	71.4
12	0.007	0.029	75.9	0.005	0.019	73.7	0.005	0.029	82.8
13	0.010	0.048	79.2	0.007	0.048	85.4	0.005	0.048	89.6
14	0.010	0.038	73.7	0.008	0.038	79.0	0.008	0.038	79.0
15	0.004	0.013	69.2	0.002	0.013	84.6	0.002	0.013	84.6
Mean	0.009	0.034	72.8	0.007	0.032	77.7	0.006	0.034	79.7

> 99% [21], differing from our findings. We believe this is likely related to the needle holes in the grid, which are left unprotected by the shield in order to allow for needle placement, and therefore remain exposed, leading to higher radiation exposure detection than would be expected with a solid shield without any exposed holes.

Though personal shielding is not a new concept in radiation therapy, as is evident by the vast market full of leaded aprons, thyroid shields, gloves, glasses, and even underwear, this is, to our knowledge, the first published device with the intention of reducing radiation exposure to the performing physician via a perineal shield. This approach has several theoretical benefits. First, as with all protection devices, they are only useful if they are actually used. Universal compliance with standard leaded personal shielding is less than ideal [22-24]. These personal articles tend to be heavy and uncomfortable, encumbering the brachytherapist for the duration of the case. Our shield does not burden the practitioner during implant and is easy to use. Second, various personal protective devices are worn adjacent to the intended site or organ of protection. Thus, protection is only afforded to a specific site. By placing our shielding closer to the source, we are able to effectively reduce exposure to a wider area due to shielding at a point with less divergence from the source. Third, personal protective shielding, particularly leaded gloves, have been shown to reduce manual dexterity [25]. No such problem exists with this device, as it is fully compatible with a commercially available template grid, and is non-restrictive with respect to needle placement. A final benefit of this device is that it is able to be used in combination with the above mentioned protective devices, in order to afford even greater protection to the brachytherapist. This is in agreement with the "As-Low-As-Reasonable-Achievable (ALARA)" concept, which was first introduced as an innovative recommendation by the National Council on Radiation Protection and Measurements (NCRP) in 1954 [26,27].

While our shield is highly effective in reducing radiation exposure during brachytherapy, the actual clinical relevance of further reducing such already low exposure rates remains unknown. Per the International Commission on Radiological Protection (ICRP), the occupational exposure of a radiation worker is to be limited to not more than 50 mSv per any one year, and to average not more than 20 mSv per year over a five year period [28]. In our study, the average dose measured at the midline grid was 0.362 mSv/hr without the shield, and 0.077 mSv/hr with the shield in place. If one were to make a conservative estimate that for every brachytherapy case, there is an average of 15 minutes of exposure to this dose, then for the brachytherapist performing 50 cases per year there would be an exposure of approximately 4.5 mSv without the shield and 1 mSv with the shield. While quantitatively, both of these exposures are low and well below ICRP recommendations, there is no known "safe" exposure. A recent article Sutlief *et al*. reviewed the stochastic effects of radiation at low exposure and the subsequent development of secondary malignancy [29]. The authors argue that the validity and applicability of the commonly used linear non-threshold model is not verified at such low doses, thus limiting the ability to draw conclusions about the risks of low rate exposure. A recent multinational, retrospective cohort study of over 400 000 nuclear industry workers revealed that low dose chronic occupational exposure to external radiation did result in an excess risk of cancer, likely accounting for 1-2% of cancer deaths in this population [30]. Thus, even the seemingly low doses of radiation the brachytherapist is exposed to during each case, could potentially cause devastating events such as radiation induced carcinogenesis.

Conceivable detriments to the use of the device are limited. Increased dose to the patient due to backscatter is possible. However, prior studies attempting to quantify backscatter exposure with Iridium-192, a higher energy source than Iodine-125 have revealed that the backscatter dose is essentially negligible at > 1 mm [31]. For our shield, it is practically difficult to measure the radiation exposure on the patient's side of the shield due to the radiation emitted directly from the sources inside the prostate. However, between the shield and the patient is the template grid itself, which measures 1 cm in width, and therefore likely provides more than enough distance to make the risk from backscatter inconsequential.

Conclusions

This novel shield is easy to use, installs in seconds, and doesn't interfere at all with the brachytherapy procedure. In agreement with the ALARA principle, it allows for at least a four-fold reduction in radiation exposure to the brachytherapist performing the seed implant without any credible harm to the patient or medical staff.

Disclosure

Authors report no conflict of interest.

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