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Research Paper

Comparative effectiveness of the EggNest complete shielding system to standard shielding in the Cath lab

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A B S T R A C T

Background: This study evaluated the effectiveness of scatter radiation reduction with the EggNest Complete shielding system compared to standard catheterization laboratory shielding.

Methods: Vertical poles with mounted radiation survey meters were positioned at six points around a catheterization laboratory imaging table where procedural staff usually stand. Meters were mounted on vertical tracks where the sensor could be raised on the track with stops every 20 cm (up to 200 cm). Fluoroscopy (15 frames per second) was then performed on an anthropomorphic phantom with a cardiac silhouette in PA and four quadrant angulations using a Toshiba Infinx fixed C-arm X-ray system with a 12″ detector. Scatter radiation measurements were reported in μSv/h under three radiation shielding conditions: no shielding, standard catheterization laboratory lead shielding, and the EggNest Complete system.

Results: Average scatter radiation levels in all angulations were significantly higher below the x-ray table and at the positions near the head of the table (1862 ± 340 μSv/h at the head vs. 605 ± 316 μSv/h below the phantom waist, $p < 0.05$). Using the EggNest Complete system compared to standard shielding, average radiation exposure in all x-ray angulations and positions was reduced by 92.5 ± 3.9 % (83 ± 103 compared to 1087 ± 898 μS/h, $p < 0.01$). At the Operator and Assistant positions, scatter radiation averaged 9 ± 4 μSv/h using the EggNest Complete (98 ± 1 % reduction compared to no shielding, $p < 0.01$), 147 ± 101 μSv/h using Standard Shielding (75 ± 8 % reduction compared to no shielding, $p < 0.01$), and 605 ± 316 μSv/h without shielding.

Conclusion: Compared to standard shielding, the EggNest Complete system significantly reduced radiation levels at all positions around the x-ray table. At the operator and Assistant positions, EggNest complete provided 98 % reduction in scatter radiation dose.

1. Background

The cardiac catheterization laboratory ("cath lab") facilitates a wide range of diagnostic and therapeutic procedures. However, the use of fluoroscopy during these procedures raises significant safety concerns for both patients and healthcare personnel. Scatter radiation exposure for personnel in the procedure room has been associated with a 3-fold increase in the incidence of various cancers and a 6-fold increase in the incidence of cataracts [1–4]. These risks have become increasingly apparent despite the use of standard radiation shielding in the room. With the increasing complexity of catheter-based interventions and subsequent cumulated radiation exposure over an entire career, the importance of radiation safety for healthcare workers has become paramount.

In addition to table and ceiling mounted lead shields, wearable apron shields are commonly utilized as radiation barriers in the cath lab and can remove between 80 and 97 % of the incident radiation, depending on the "lead equivalency" of the shield [5]. However, aprons do not cover the head, neck, arms, lateral breast, or lower legs, leaving these areas exposed to substantial scatter radiation. In addition to their imperfect radiation protection, they also result in significant orthopedic injuries with longitudinal use, with roughly half of interventional cardiologists reporting at least one major orthopedic injury during their career [6].

Novel radiation protection systems may substantially reduce the amount of scatter radiation that workers in these rooms are exposed to without increasing the likelihood for orthopedic injury. The EggNest Complete shielding system (Egg Medical, Inc., Arden Hills, MN, USA) utilizes a series of modular shields around, above, and under the table to improve reduction in scatter radiation across the procedure room. This study aimed to compare the effectiveness of the EggNest Complete shielding system versus standard cath lab shielding in reducing scatter radiation.

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2. Methods

2.1. X-ray C-arm unit

A fixed C-arm X-ray system (2013 Toshiba InfinX, Toshiba America, Tustin, CA) with a 12″ detector was utilized for this study. The fluoroscopy control was set at 15 frames/s with a fixed X-ray tube output consisting of tube voltage of 70 kV, filament current of 3.2 milliamps, and pulse width of 6.7 milliseconds. The collimators were brought in during measurements to approximate the edge of the imaging detector.

2.2. X-ray phantom

We used an anthropomorphic phantom obtained from the U.S. Department of Energy Phantom Library Model RESL201 (Idaho Falls, Idaho, USA). The anthropomorphic phantom generated scatter radiation that approximated that generated by a large human subject [7].

2.3. Measurement of scatter radiation

Radiation levels were measured in μSv/h using six mounted solid-state survey meters (X2 Survey Sensor, Raysafe, Hovås, Sweden) positioned where cath lab staff usually stand during various types of procedures (Fig. 1). In a prior study, measurements from this survey meter were demonstrated to have a reproducibility of ±3.3 % (95 % confidence interval) ($r^2 = 0.996$) [8].

The meter sensors were affixed to holders mounted on vertical tracks on calibrated poles, 200 cm in height, where the sensor could be raised on the track with stops at every 20 cm (20 to 200 cm). The positions 20–40 cm above the floor were labeled as representing the radiation that would reach the lower legs and feet, 60-140 cm as the radiation that would reach the thighs and body, and 160–200 cm as what would reach the head and neck. This set-up ensured that the angle and vertical height of the sensor was repeatable between measurement condition.

2.4. Shielding conditions

Scatter radiation was measured under three shielding conditions: no shielding, using standard cath lab shielding, and using the EggNest Complete radiation shielding system.

Standard shielding consisted of a table-mounted lead drape for the operator and a ceiling-mounted acrylic shield (Mavig Model OT50001). Each had 0.5 mm lead equivalence. The table shield (90 by 69 cm) was mounted to a rail on the X-ray table pedestal. The shield was placed in the standard position for a radial access case. The clear acrylic ceiling-mounted shield was placed such that the standard cutout approximated the junction between the anthropomorphic phantom leg and torso (the "hip").

The EggNest Complete shielding system consisted of a carbon fiber-based platform that is mounted onto the X-ray table (Egg Medical, Inc., Arden Hills, MN, USA; Fig. 2). Flexible shielding (0.5 mm lead equivalence) below the table is affixed to the platform such that there is a radiation shield around the sides and head of the table that moves with the C-arm gantry. In addition, flip shields (0.5 mm lead equivalence) around the table can be rotated upwards after the patient is moved to the X-ray table to provide shielding around the patient. A ceiling- or boom-mounted clear acrylic shield (the Complete Shield) with 1.0 mm lead equivalent shielding is placed over the patient, such that a cutout with a radiation shielding fringe is placed against the patient and extends across the arm. The right arm is held in a cradle with additional radiation shielding.

2.5. Experimental protocol

The table with the phantom was positioned such that the phantom heart and the upper edge of the diaphragm were in the 12″ imaging field. During imaging at each X-ray angulation, scatter radiation measurements were obtained at 20 cm increments from 20 cm above the floor to 200 cm in each position. For each shielding condition, measurements at all six positions around the table were taken in the following X-ray angulations: PA, RAO 30/Cranial 20, RAO 30/Caudal 20, LAO 30/Cranial 30, and LAO 40/Caudal 20.

2.6. Statistical analysis

Average or summed values are expressed as mean ± standard deviation. Differences in paired scatter radiation intensity measurements between each of the shielding conditions were analyzed with analysis of variance. A p-value <0.05 was considered statistically significant.

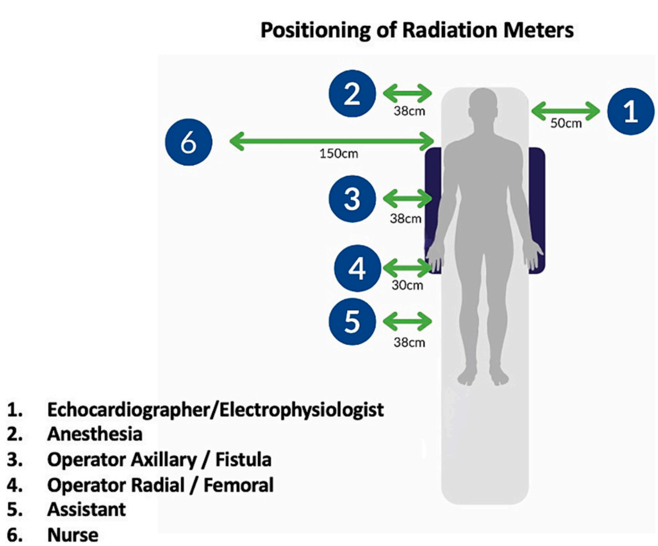

Fig. 1. Positioning of radiation meter poles used for study, simulating various catheterization laboratory staff positions.

Fig. 2. The EggNest Complete radiation protection system. Flexible shielding (0.5 mm lead equivalence) below the table is affixed to the platform such that there is a radiation shield around the sides and head of the table that moves with the C-arm gantry. In addition, flip shields (0.5 mm lead equivalence) around the table can be rotated upwards after the patient is moved to the X-ray table to provide shielding around the patient. A ceiling- or boom-mounted clear acrylic shield (the Complete Shield) with 1.0 mm lead equivalent shielding is placed over the patient, such that a cutout with a radiation shielding fringe is placed against the patient and extends across the arm. The right arm is held in a cradle with additional radiation shielding.

3. Results

Scatter radiation was not uniformly distributed around the x-ray table. Without shielding, average scatter radiation levels in all angulations were significantly higher below the x-ray table (1127 ± 111 μSv/h below the table vs. 789 ± 139 μSv/h, $p < 0.01$) and at the positions near the head of the table (1974 ± 395 μSv/h at the head vs. 605 ± 316 μSv/h below the phantom waist, $p < 0.01$).

3.1. Effect of standard and EggNest Complete shielding on scatter radiation measurements

Average radiation scatter measurements (across all heights for each position around the table in each C-arm angulation) using the three shielding conditions can be seen in the Graphical abstract. The EggNest complete system provided an average of 92.4 ± 3.8 % reduction in scatter radiation measurements in all C-arm positions compared to no shielding and 92.4 ± 3.8 % reduction compared to standard shielding ($p < 0.01$ for all positions).

Absolute reductions in scatter radiation dose measurements when using the EggNest Complete system compared to no shielding and standard shielding for each position around the table in each c-arm position can be seen in Tables 1 and 2.

3.2. Height and table position effects on radiation scatter measurements

Average radiation dose levels in the primary operator and assistant positions using the EggNest Complete system were 12 ± 5 and 7 ± 1 μSv/h, respectively. This represents a 98.7 ± 0.4 % and 97.8 ± 0.1 % reduction in radiation dose with the EggNest Complete system compared to the no shielding condition (all comparisons, $p < 0.01$) and a 95.6 ± 2.3 % and 91.2 ± 2.2 % reduction in radiation dose compared to the standard shielding condition (all comparisons, $p < 0.01$).

The average scatter radiation levels for Positions 1, 2 and 3 near the head of the table were significantly lower using the EggNest Complete (151 ± 128 μSv/h) compared to standard shielding (1960 ± 360 μSv/h, $p < 0.01$ vs EggNest), and no shielding (1974 ± 395 μSv/h, $p < 0.01$ vs EggNest).

Additionally, there was an unequal distribution of radiation at various height measurements, with higher measurements in the body and thigh regions compared to the feet and head in most c-arm angulations, particularly around the head and left side of the bed (Figs. 3, 4). Notably, there were significant reductions in scatter radiation measurements for all body parts in each c-arm angulation tested when using the EggNest Complete system compared to standard shielding ($p < 0.01$).

4. Discussion

This study evaluated real-time radiation scatter measurements around a standard cath lab table at various heights and positions around the table using three different scatter radiation protection conditions: no shielding, standard cath lab lead shielding, and the EggNest Complete radiation protection system. The results illustrate significant reductions in scatter radiation doses when using the EggNest Complete system compared to no shielding and standard cath lab shielding. These results were consistent at various positions around the table, C-arm angulations, and heights corresponding to different regions of the body for all staff members working in the cath lab.

Several novel radiation protection systems have been shown to reduce scatter radiation doses compared to standard cath lab shielding [9–11]. While it is encouraging that an increasing number of these systems are commercially available, there are several important components of the ALARA ("as low as reasonably achievable") principle that must be central to any radiation protection system. First, it has to offer more protection than the current gold standard (i.e. standard cath lab shielding). Second, it needs to protect everyone in the room (all positions around the table), not just the primary operator and assistant positions. Third, it should be scalable to the myriad of procedures performed in modern day cath labs, as many of these rooms are "mixed use"- this means the system must provide protection for those performing cardiac cath procedures, structural heart procedures,

Table 1
Absolute scatter radiation measurement comparisons for the EggNest Complete system compared to no shielding and standard shielding (all averaged values for EggNest Complete were $p < 0.01$ vs standard shielding and no shielding).

Position	1	2	3	4	5	6	Average	SD
X-ray angle	Echo/EP implanter	Anesthesia/jugular access	EP assistant	Operator	Assistant	Nurse		
Absolute scatter radiation dose with no shielding (μSv/h)								
PA	1620	1945	2151	980	320	323	1223	733
RAO 30/Cranial 20	1568	2280	1811	945	297	378	1213	734
LAO 30/Cranial 30	1400	1837	2594	594	237	332	1166	859
RAO 25/Caudal 20	1672	1957	1789	867	341	387	1169	664
LAO 30/Caudal 20	1663	2682	2640	1097	376	385	1474	948
Average	1585	2140	2197	897	314	361	1249	774
SD	99	309	366	169	46	28	115	
Absolute scatter radiation dose with standard shielding (μSv/h)								
PA	1666	2004	2121	164	92	319	1061	882
RAO 30/Cranial 20	1418	1808	2300	194	81	326	1021	862
LAO 30/Cranial 30	1418	1808	2300	194	81	326	1021	862
RAO 25/Caudal 20	1735	1909	1971	107	67	390	1030	851
LAO 30/Caudal 20	1706	2604	2628	416	72	382	1301	1061
Average	1589	2026	2264	215	78	349	1087	898
SD	141	298	220	105	9	31	108	
Absolute dose with EggNest Complete system (μSv/h)								
PA	45	354	39	8	6	30	80	123
RAO 30/Cranial 20	76	150	43	10	7	24	52	50
LAO 30/Cranial 30	47	332	63	7	5	24	80	115
RAO 25/Caudal 20	85	240	188	11	7	32	94	90
LAO 30/Caudal 20	100	449	56	21	9	32	111	154
Average	71	305	78	12	7	28	83	103
SD	22	102	56	5	1	4	20	

Table 2
Percent reduction in scatter radiation using the EggNest Complete system compared to no shielding, by position around the X-ray table and X-ray angulation. All values are $p < 0.01$ for EggNest Complete system vs. no shielding and EggNest Complete system vs. standard shielding.

Position	1	2	3	4	5	6	Average	SD
X-ray angle	Echo/EP implant	Anesthesia/jugular access	EP assistant	Operator	Assistant	Nurse		
EggNest Complete system % reduction in scatter radiation dose compared to no shielding								
PA	97 %	82 %	98 %	99 %	98 %	91 %	94 %	6 %
RAO 30/Cranial 20	95 %	93 %	98 %	99 %	98 %	94 %	96 %	2 %
LAO 30/Cranial 30	97 %	82 %	98 %	99 %	98 %	93 %	94 %	6 %
RAO 25/Caudal 20	95 %	88 %	89 %	99 %	98 %	92 %	93 %	4 %
LAO 30/Caudal 20	94 %	83 %	98 %	98 %	98 %	92 %	94 %	5 %
Average (±SD)	96 %	86 %	96 %	99 %	98 %	92 %	94 %	4 %
SD	1 %	4 %	3 %	0 %	0 %	1 %	1 %	
EggNest Complete system % reduction in scatter radiation dose compared to standard shielding								
PA	97 %	82 %	98 %	95 %	93 %	91 %	93 %	5 %
RAO 30/Cranial 20	95 %	92 %	98 %	95 %	92 %	93 %	94 %	2 %
LAO 30/Cranial 30	97 %	82 %	97 %	96 %	93 %	93 %	93 %	5 %
RAO 25/Caudal 20	95 %	87 %	90 %	90 %	89 %	92 %	91 %	2 %
LAO 30/Caudal 20	94 %	83 %	98 %	95 %	88 %	92 %	92 %	5 %
Average (±SD)	96 %	85 %	97 %	95 %	91 %	92 %	92 %	4 %
SD	1 %	4 %	3 %	2 %	2 %	1 %	1 %	

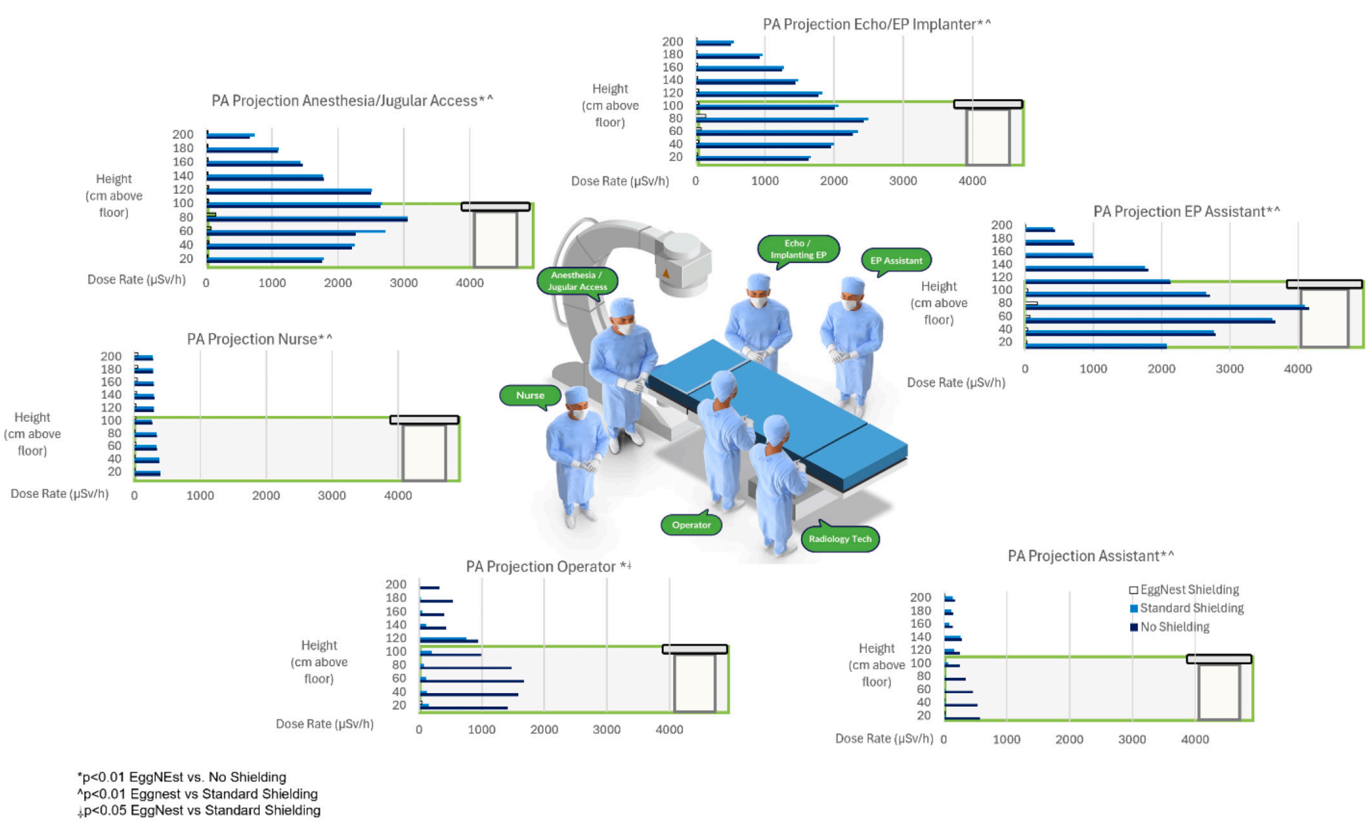

Fig. 3. Absolute scatter radiation measurements taken at various heights using no shielding, standard shielding, and the EggNest Complete system for the PA C-arm angulation. Average radiation levels using the EggNest Complete system were significantly lower than radiation levels using standard shielding or no shielding.

endovascular procedures, ablations, device implants, interventional neurology procedures, interventional radiology procedures, among others. This study illustrates that the EggNest Complete system provided significant protection for all positions in the room using standard c-arm angulations and could be utilized in the various types of procedures performed in today's cath lab.

There were several other interesting findings in this study. Scatter radiation was not evenly distributed around the X-ray table. Caudal angulations significantly increased total scatter radiation in the room compared to non-caudal views. Additionally, scatter radiation doses at the head of the bed were significantly greater than at other positions around the table. Compared to no shielding or standard shielding, the EggNest Complete system reduced radiation levels at all positions around the table in all X-ray angulations measured in the study. Given the unequal distribution of scatter radiation seen in this study, having a radiation protection system that protects all positions around the bed is imperative in order to protect all members of the cath lab team.

There were several limitations to this study. First, while this study presents a rigorous design, there are a variety of other study designs for measuring scatter radiation without a currently accepted standard

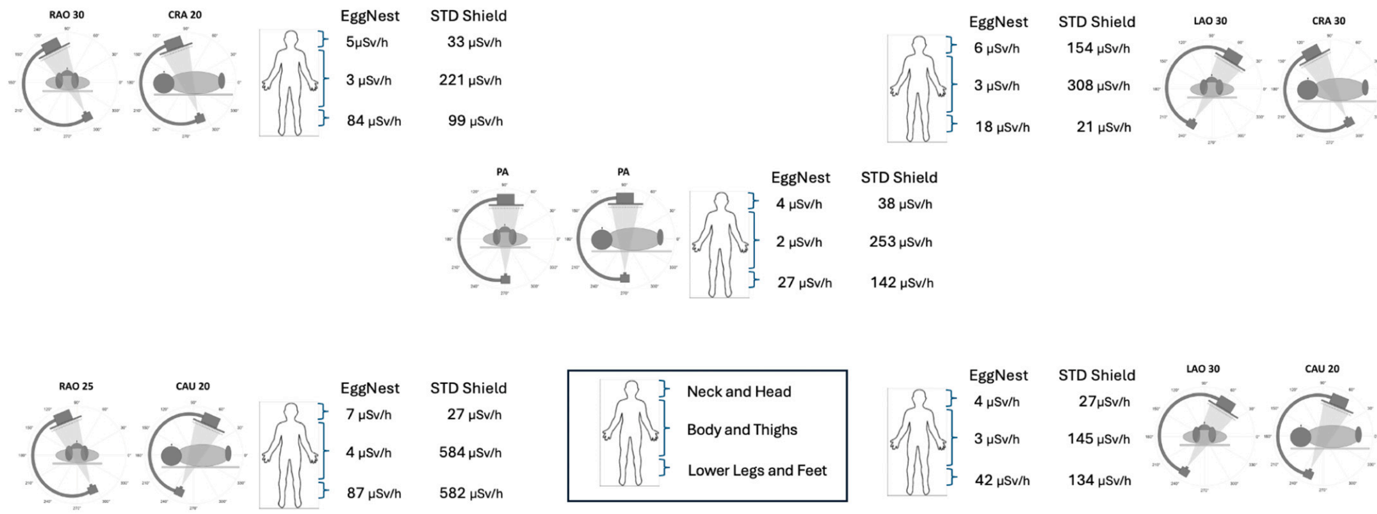

Fig. 4. Anatomy-specific aggregated scatter radiation measurements at the primary operator position (Position 4) at various C-arm angulations using standard shielding compared to the EggNest Complete system. For all C-arm angulations, $p < 0.05$ for 20–180 cm aggregate measurements for EggNest versus standard shielding.

method. Second, these measurements were recorded using an anthropomorphic phantom. Although the phantom employed has scatter properties similar to that of humans, the magnitude of scatter radiation is dependent on the radiodensity of the specific X-ray target within the body. Humans of different sizes will generate smaller or larger absolute radiation levels, and imaging the abdomen or other areas may result in different scatter radiation patterns [12]. The results from this study will need to be confirmed in future clinical studies.

5. Conclusion

Compared to standard cath lab shielding, the EggNest Complete radiation protection system showed significant reductions in scatter radiation measurements in all measured conditions, including common C-arm angulations as well as clinically relevant heights and positions around the table. Incorporating the EggNest Complete system in the cath lab could significantly reduce the risk of radiation-related occupational hazards for all members of the cath lab team.

CRediT authorship contribution statement

Robert F. Riley: Formal analysis, Supervision, Writing – original draft, Writing – review & editing. **Jacob Kamen:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Ashley Tao:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. **Daniel Gomez-Cardona:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing.

Ethical statement

As the use of human subjects was not utilized for this study, IRB approval was waived at the University of Minnesota.

Declaration of competing interest

Drs. Riley, Kamen, Tao, and Gomez-Cardona serve as advisors for Egg Medical, the sponsor of this study.

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