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A Lead Garment Structural System to Reduce Musculoskeletal Stress During Fluoroscopy

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Cardiovascular, orthopedic, and interventional radiology procedures using fluoroscopy require healthcare professionals to wear heavy lead garments for radiation protection, which can lead to musculoskeletal injuries, discomfort, and fatigue. A mobile lead garment frame, MobiLead, was designed to mitigate these issues by moving the lower garment load off body to a structural frame and redistributing the load of the upper garment from the shoulders to the hips through a torso frame. The frame was designed to be compact with a minimal footprint for maneuverability in operating rooms with limited space, while still giving the surgeon adequate mobility for various emergency procedures. Preliminary analysis of device efficacy was conducted using electromyography (EMG) of load-bearing muscles during use and qualitative surgeon user feedback surveys. Nonparametric permutation tests showed that the MobiLead device mean activation was significantly lower than the standard lead garment (p < 0.001). Surgeon feedback and use testing showed that the device fits under a sterile gown and is maneuverable in an operating room (OR).

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Background

Many common surgical procedures rely on fluoroscopy, an imaging technique which uses a continuous X-ray stream to image the skeletal, digestive, urinary, respiratory, and reproductive systems. Examples of common surgical uses are cardiac catheterization, lumbar puncture, angiograms, fracture alignment, and placement of intravenous catheters. While fluoroscopy provides significant benefit during surgery, the risk of occupational radiation exposure is high, and thus, requires surgeons and attending staff to wear radioprotective equipment. The gold standard for radiation protection is the one or two piece lead garment, which can weigh as much as 40 lbs and be worn for up to 10 h per day. Long-term use of lead garments for prolonged periods can lead to an array of ergonomic complications, including discomfort, fatigue, and musculoskeletal injuries. The occupational health risks of wearing radioprotective equipment are becoming more widely recognized and have been termed “an epidemic of orthopedic complications”[1]. Studies have shown a 75% increased incidence of spine problems in interventionalists compared to medical specialists that do not wear lead[2], and a prevalence of orthopedic complaints: 42% of interventionalists complained of spine injuries and 28% suffered from hip, knee, and ankle injuries[3].

A mobile lead garment frame, MobiLead, was developed to reduce the weight supported by the user when wearing a lead garment in an effort to mitigate orthopedic problems. As shown in Fig. 1, the two-part MobiLead system moves the lower garment load off the user’s body to a structural ground-supported frame and redistributes the upper load from the shoulders to the hips through a torso frame. The upper and lower frames are compact and maximize the limited space available in operating rooms (OR), while still giving the surgical team adequate mobility for various emergency procedures.

A review of the literature and prior art showed that the most commonly used radiation protection system in hospitals is the two-piece lead garment, composed of a vest and skirt, which effectively blocks radiation exposure to the core, chest, and reproductive organs[4] and qualitatively allows for the necessary range of motion during surgery. This two-piece lead garment typically weighs 15–40 lb, which the surgeon supports on their shoulders and waist. Lead garments can be worn for up to 10h a day, leading to short-term musculoskeletal fatigue and longitudinal injury primarily to the neck, lower back, hip, knee, and ankle[5].

Two commercial options, the ZeroGravity from Biotronik Se & Co. KG (Lake Oswego, OR) and the Cathpax® AF Telescopic Radiation Protection Cabin from Lemer Pax (La Chapelle-sur-Erdre, France), seek to solve muscle fatigue issues by providing off-body lead garment support, but neither device addresses other

Fig. 1 MobiLead is a modular system, meaning the skirt frame can be used with the framed vest, or each can be used independently with a traditional lead garment.
important surgeon and hospital specifications, such as mobility, patient proximity, and cost requirements. The ZeroGravity system alleviates orthopedic strain by suspending a lead garment from the ceiling or a crane. In one configuration, the garment follows the movements of the surgeon by rolling on ceiling-mounted linear guide rails. While this device does remove the weight of the garment from the surgeon, it restricts mobility, protects a single person, does not cover the user’s backside, can be incorrectly positioned too low on the user’s body (resulting in radiation exposure to the thyroid), and is costly to purchase and install. Alternatively, the Cathpax encases the physician with leaded glass on three sides. Although studies show that the cabin provides adequate radiation protection and musculoskeletal relief [5], the cabin footprint and rigid construction restricts mobility during procedures, separates the surgeon from the patient, is bulky to store and move in the operating room, and only provides protection for one person. An alternative solution is desired that can meet all needs of the hospital and surgical team.

**Methods**

A deterministic design process was conducted to develop the MobiLead system. Functional requirements (Table 1) for the device were identified through discussions with key stakeholders, including hospital staff who routinely wear lead garments and hospital ergonomic specialists. In addition to meeting radiation protection specifications, users wanted a system that could provide musculoskeletal relief and be mobile, space efficient, and affordable. Mobility was prioritized as an important requirement in constrained ORs with multiple obstacles on both the floor and the ceiling. Furthermore, multiple practitioners using the device concurrently must move smoothly around each other.

After identifying functional requirements, the primary strategy chosen was redistributing the lead garment weight. This strategy was selected as more promising than changing the garment material or shielding the radiation beam in a way that prevented exposure to the medical provider. The ceiling, floor, and wall were considered as potential mounting points for the support mechanism. To choose one of these, an observational study was conducted of three ORs to evaluate potential for mounting and support, accessibility, sterility, storage, and full surgeon mobility. Ceiling-mounted designs were eliminated because of the numerous other devices mounted that would need to be navigated, variable layouts in operating rooms, and a high installation cost. Wall-mounted designs were eliminated because most walls in the OR have either windows or cabinet storage space, limiting the potential places for mounting. Floor-supported designs, while challenging from a navigation perspective in small spaces, allow for the radioprotective garment to be worn under the user’s sterile gown, thus eliminating the need for additional sterile coverings that are often cumbersome and expensive.

An on-body vest with internal frame was chosen to support the upper protective garments. Separating the upper and the lower support maintained maximum mobility, particularly when bending at the waist. This design decision was supported by studies that showed that distributing weight to the hips decreased muscle activity and reduced fatigue in back muscles during neutral and leaning postures [6–8].

The MobiLead design comprises a two-part modular frame support system, as shown in Fig. 1. The upper frame redistributes the vest garment weight from the shoulders to the hips via a rigid torso frame and hip belt [8,9], as shown in Fig. 2. The lower frame fully supports the skirt weight and rolls on the floor, as shown in Fig. 2. System modularity allows the surgeon to maintain full bending ability at the waist while providing off-body lead garment support to reduce fatigue. Furthermore, this modular system allows surgeons to choose the combination that is most effective for their body type and work (Fig. 3).

The inspiration for the vest redesign came from an internal frame backpack in which the frame transfers the weight of the backpack to the user’s hips. The new vest design incorporates a rigid frame into a traditional vest to take the weight off the user’s shoulders. When donning the vest, the user must fasten and cinch a waist belt before closing the vest, but otherwise the steps to put on the MobiLead vest are the same as those with a conventional vest. This intuitive similarity lowers the barrier to entry for adoption. Velcro or magnets are used to attach the frame to the vest. This adjustable attachment allows the vest to be functional with and without the frame, depending on user preference and case-dependent requirements.

Manufacturers and hospitals establish guidelines about how to hang lead garments to prevent the lead from fracturing and becoming less effective, but these best practices are often not followed because of space constraints, and it takes more time to store the garments properly, according to observations made in

<table>
<thead>
<tr>
<th>Functional requirement</th>
<th>Description</th>
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<tr>
<td>Reduces fatigue</td>
<td>Reduces weight supported by the back and neck</td>
</tr>
<tr>
<td>Mobile</td>
<td>Wide range of movement for surgical procedures</td>
</tr>
<tr>
<td>Sterile</td>
<td>Meets CDC hospital sterility standards, easily sterilized</td>
</tr>
<tr>
<td>Provides radiation protection</td>
<td>Provides equal or better radiation protection than current lead garment alternatives</td>
</tr>
<tr>
<td>Intuitive</td>
<td>Design encourages proper use and is simple to put on</td>
</tr>
<tr>
<td>Space efficient</td>
<td>Fits with operating room furniture and machines</td>
</tr>
</tbody>
</table>

![Image](image-url) Fig. 2 The internal frame of the lead vest comprises a rigid frame, padding, and an adjustable waist belt
hospitals and interviews with nurses at Brigham and Women’s Hospital (Boston, MA). The upper frame reduces potential damage to the lead by providing structure to the vest even when it is not being worn which prevents folding and cracking of the lead. Furthermore, when the lead garments are replaced, both the upper and the lower frame can be reused.

The skirt frame, shown in Fig. 3, is a bent and welded steel pipe structure, weighing less than 4 lb, with four legs, a vertical support behind the user, and a C-shaped frame around the user’s waist, which supports a lead skirt (Fig. 2). Ball transfer wheels allow movement in all directions, and the wheels are located to provide stability, ergonomic area for foot and leg mobility, and spaced such that the axis of rotation of the device aligns with that of the user. To design for stability, the front and rear wheel placement was calculated using a free body diagram of the system, such that the frame is stable under the distributed weight of the lead garment across the waist frame. The free body analysis simplified the skirt frame structure into a cantilevered design with a distributed load representing the lead skirt. With a maximum force load of 10 kg for the skirt portion, the necessary lengths of the wheel legs to balance the moments were determined. Observations showed the structure moving more fluidly with the user when the axis of rotation of the wheels is aligned with the user’s center. Furthermore, the center of stiffness of the bottom frame aligns with the human axis of symmetry, thus aligning the force about the vertical line of symmetry, as illustrated in Fig. 4.

To don the lower frame, the user opens the front of the skirt, steps in, and reattaches the skirt to provide full coverage. The frame attaches to the sides of user’s lead vest with Velcro or magnets so that the bottom structure moves with the user as they walk or turn. Prior to a procedure, the height of the lower frame can be adjusted so that it can fit a wide range of users. The off-body, ground-supported skirt design can support a thicker lead skirt, increasing user safety, because conventional lead garments often have thinner lead at the back to reduce weight. Testing in an operating room showed that the frame translates and rotates with the user and the ball transfer wheels move over bundles of wires on the ground. Figures 5 and 6 show a user testing the ergonomics and mobility of the device in an operating room.

Human factors and ergonomic considerations are an integral part of the design in order to meet key surgeon specifications, as well as fit a range of body types, shapes, and sizes. The top portion of the skirt frame consists of two interchangeable waist segments,
the small size designed to fit 5–50 percentile persons, and the large designed for 50–95 percentile persons [10]. The front opening of the waist segment allows for entrance and exit of the device, shown in Fig. 2. This top portion can be easily removed and replaced by the user depending on size selection. Height adjustability specifications required 12 in. of adjustability with a 35 in. minimum and 48 in. maximum waist height to provide protection for the 1–99 percentile human [10]. This adjustability was attained by telescoping tubes constrained by a removable T-handle lock pin at 1 in. adjustment intervals. The pin was chosen for ease of manufacturing and design for initial prototypes.

Evaluation

Quantitative electromyography (EMG) was used to measure muscle fatigue. According to prior muscle fatigue studies, EMGs are the best quantitative, objective tool for studying the mechanisms underlying muscular discomfort or fatigue reported by laparoscopic surgeons [11]. The EMG monitor selected connects wirelessly with noninvasive surface EMG electrodes. Muscle activity was measured and compared for three scenarios: a control in which the user did not wear any protection, the standard with the user wearing a traditional two-piece lead garment, and the new solution using the MobiLead system. The EMG data provide insight into the muscle activity through the root-mean-square, which measures the power of the signal from the electrode. The root-mean-square value is positively correlated with muscle activity. These EMG tests assessed the upper trapezius muscles, which have been shown to be fatigued by backpack-like loads [6]. A subject was tested with two EMG electrodes, one on each upper trapezius. To isolate muscle groups and avoid interference from nearby muscles, calibration was conducted on each subject by placing the electrode around the muscle body until the signal was clear and easy to discern. Each session lasted for 30 min, and the subject stood at a 36 in. tall workbench, approximately surgical table height, using a laptop or writing in a notebook for the duration of the test.

The observed EMG signals (Fig. 7) when plotted as a histogram (Fig. 8) were highly skewed to outliers in each scenario. Accordingly, a one-tailed permutation test (a nonparametric test) was used to compare the mean muscle activity between each scenario ($n = 350$, permutations = 100,000). The mean activations for the control, device, and standard lead garment were 5.81, 4.88, and 9.95, respectively (Table 2).

Mean muscle activation was significantly larger when using a standard lead garment than when using the MobiLead device ($p < 0.001$). Similarly, mean muscle activation was significantly larger for the standard lead as compared to the control ($p < 0.001$). Curiously, the MobiLead device significantly reduced mean muscle activation when compared to the control ($p < 0.001$). Since only one trial was conducted for each scenario, outlier movements could explain some of the unexpected difference between control and MobiLead. Moreover, the significance test (i.e., $p$-values) reported against a hypothesis of no-effect. While some changes were observed between the control and device runs, the observed mean shift between MobiLead and control was only $9.30 \times 10^{-7}$ V, 4.45 times smaller than the observed shift between control and lead. Future testing of MobiLead should prioritize gathering a larger set of independent samples, with multiple replications of each run.

This overall structural design was developed collaborating closely with a cardiologist who has extensive experience performing procedures while wearing lead garments. Qualitative user testing was performed with a mock case. Positive feedback included that the device fully removed the weight of the lead skirt off the body, thus improving comfort; the frame could smoothly move over cables in the floor; and the device was easy to navigate hands free via the vest attachments. Constructive criticism indicated that the frame sometimes interfered with the user’s calves, and the Velcro on the front of the skirt was difficult to close. The subsequent iteration of the design addresses these drawbacks.

Discussion

MobiLead removes the load of the lead skirt off the surgeon and redistributes the remaining vest load from the shoulders to the hips. In doing so, MobiLead may reduce the risk of fatigue and
longitudinal injury for the surgeon. Comparing mean muscle activation for the control, standard lead, and MobiLead demonstrated positive preliminary EMG test results that show that using MobiLead reduces trapezius muscle activity compared to the standard two-piece lead garment.

Limitations of the preliminary evaluation presented include small sample sizes for the EMG fatigue testing and that the device has not been formally evaluated during an operative procedure. Future EMG testing should gather a larger set of independent samples, with multiple replications for each run, as well as test more muscles for activation and fatigue in the shoulders and lower back.

Acknowledgment

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Table 2 Mean activation and standard deviation of the EMG data

<table>
<thead>
<tr>
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<th>Activation (Volts $\times 10^{-6}$) mean (s.d.)</th>
</tr>
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<tbody>
<tr>
<td>Control</td>
<td>5.81 (1.24)</td>
</tr>
<tr>
<td>Lead</td>
<td>9.95 (6.43)</td>
</tr>
<tr>
<td>Device</td>
<td>4.88 (1.09)</td>
</tr>
</tbody>
</table>

Note: s.d.: standard deviation.

References