A Novel Lead Garment Structural System to Alleviate Orthopedic Stress for Surgeons

Proceedings of the 2018 Design of Medical Devices Conference
DMD2018
April 9-12, 2018, Minneapolis, MN, USA

DMD2018-6920

A NOVEL LEAD GARMENT STRUCTURAL SYSTEM TO ALLEVIATE ORTHOPEDIC STRESS FOR SURGEONS

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BACKGROUND

Cardiovascular, orthopedic, and interventional radiology procedures using fluoroscopy require healthcare professionals to wear heavy lead garments for radiation protection, sometimes for up to 12 hours per day. Wearing lead garments for prolonged periods of time can lead to musculoskeletal injuries, discomfort, and fatigue. MobiLead is a mobile lead garment frame that was developed to reduce the weight supported by the user in an effort to mitigate these problems. The 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 system is compact and maximizes the limited space available in operating rooms, while still giving the surgeon adequate mobility for various emergency procedures. Preliminary analysis of device effectiveness was conducted using electromyography and qualitative surgeon user feedback surveys. This paper will discuss the design, fabrication, and testing procedures for this mobile radiation protection system optimizing both support and mobility.

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, orthopedic procedures, 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. Increased incidence of musculoskeletal pain caused by this radioprotective equipment is becoming more widely documented through research and experiential anecdotes [1].

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 [2] and qualitatively allows for the necessary range of motion during surgery. This two-piece lead garment typically weighs 15-40 pounds, which the surgeon supports on their shoulders and waist. Lead garments can be worn for up to 12 hours a day, leading to short-term musculoskeletal fatigue and longitudinal injury primarily to the neck, lower back, hip, knee and ankle [3].

Two commercial options, the ZeroGravity from BIOTRONIK, Inc. and CATHPAX Radiation Protection Cabin from Anthem Medical seek to solve weight and fatigue issues by providing off-body lead support, but both fail to address other important surgeon 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. The garment follows the movements of the surgeon by rolling on ceiling-mounted linear guide rails. While this device does fully remove the weight of the garment from the surgeon, it significantly restricts mobility, protects a single person, does not cover the user's backside, is often worn incorrectly resulting in radiation exposure, 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 [4], the cabin significantly 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. Both solutions are unsuccessful in providing a desirable alternative to the lead garment that meets the surgeon's needs.

METHODS

The design process for the MobiLead lead garment structural system began with determining key specifications for a new product based on the needs of key stakeholders, primarily surgeons and nurses in the OR who wear lead garments. Meeting the necessary radiation protection standards is a baseline requirement, but stakeholders also want their devices to provide orthopedic relief and be mobile, space efficient, and affordable. None of the state of the art technologies meet these requirements. MobiLead is a radiation protection system that prioritizes mobility, support, sterility, ease of use, cost, and surgeon ergonomics to improve the well-being and comfort of healthcare professionals who are required to wear radiation protection.

Mobility was prioritized as an important requirement in constrained ORs with wires and other obstacles on both the floor and ceiling. Furthermore, several practitioners using the device concurrently must move smoothly around each other to maximize mobility and maintain sterility.

After selecting functional requirements, the primary chosen strategy was redistributing the garment weight. This was selected as a more promising strategy 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, unpredictable layout, and a high installation cost. Wall-mounted designs were eliminated because most walls in the OR are either windows or cabinet storage space, limiting the potential places for mounting. Floor-supported designs, while challenging from a navigation perspective in small spaces, offered a unique opportunity to put the radioprotective garment close to the surgeon under their sterile gown, thus eliminating the need for additional expensive, consumable sterile coverings for the device.

An on-body vest with internal frame was chosen to support the upper protective garments. Separating the upper and 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 [4-6].

The final design demonstrates a two-part modular frame support system. The upper frame redistributes the vest garment weight from the shoulders to the hips via a rigid torso frame and hip belt [7,8]. The lower frame fully supports the skirt weight and rolls on the floor. 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.

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 are the same as with a conventional vest. This intuitive similarity lowers the barrier to entry for adoption, and is quick to put on. Velcro is used to attach the frame to a standard vest. This adjustable attachment allows the vest to be functional with and without the frame, depending on user preference and case-dependent requirements.

There are 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 habit. The upper frame minimizes damage to the lead by holding the vest in an optimal position even when it is not being worn. Additionally, when the lead garments are biannually replaced, both the upper and lower frame can be reused.

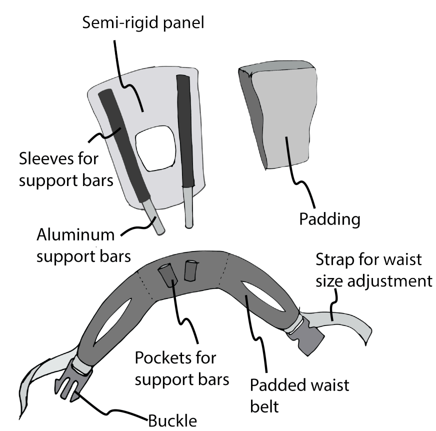

Figure 1. The internal frame of the lead vest comprises a rigid frame, padding, and an adjustable waist belt.

The skirt frame is a precision bent and welded steel pipe structure. In order to calculate stability, a free body diagram of the frame was drawn, and an analysis spreadsheet was used to calculate wheel placement of the front and rear wheels such that the frame was stable under the distributed weight of the lead garment across the waist frame, modeled as a cantilever beam. The free body analysis simplified the skirt frame structure into a cantilevered design with a distributed horizontal load indicating the lead skirt. With a maximum force load of 10 kg for the skirt portion, the necessary lengths of the wheel legs were determined. After aligning the axis of rotation of the wheels with the user's center, observations showed the structure moving more fluidly with the user. The legs of the device do not interfere with the user's feet and calves. Furthermore, the center of stiffness of the bottom frame aligns with the human axis of symmetry, thus aligning torques, moments and forces about vertical line of symmetry.

The frame itself weighs less than four pounds, and a lead skirt hangs from the frame, as shown in Figure 2. The front of the skirt opens and the user steps in and reattaches the skirt to provide full coverage. The frame attaches to the user's vest with Velcro so that the structure moves smoothly with the user as she/he walks or turns. The off-body, ground-supported skirt design can support a thicker lead skirt, increasing user safety because conventional lead garments often have thinner lead in places to reduce weight. Ball transfer wheels allow smooth movement in all directions without sticking and the height of the device is easily adjustable with a pin such that it can fit a wide range of users. Testing in an operating room showed that the ball transfer wheels move over bundles of wires on the ground.

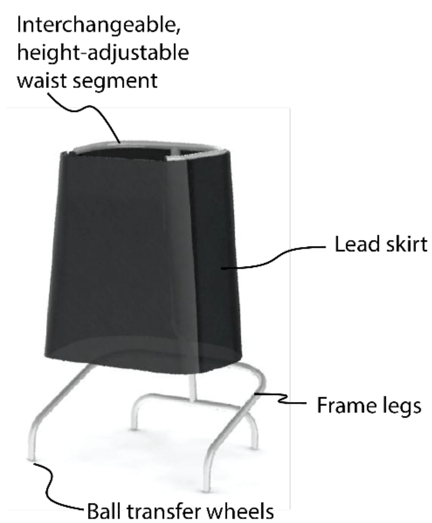

Figure 2. The skirt frame transfers the lead skirt off the user's hips and onto the ground.

Human factors and ergonomics were an integral part of the design 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 designed to fit 1-50 percentile persons, and the large designed for 50-99 percentile persons [8]. The front opening of the waist segment allows for easy 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 inches of adjustability with a 35 inch minimum and 48 inch maximum waist height to provide protection for the 1-99 percentile human [8]. This adjustability was attained by telescoping tubes constrained by a pin joint at 1 inch adjustment intervals. The pin joint was chosen for ease of manufacturing and design for initial prototypes.

RESULTS

A Trigno Mobile portable electromyogram monitor (EMG) used for quantitative electromyography was selected to measure muscle fatigue and usage. 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 [9]. The EMG monitor selected connects with six non-invasive EMG nodes that can be attached to the skin to measure muscle energy.

Taking measurements with the Trigno EMG, energy differences are evident between the three states: option one without lead, option two while wearing lead but without a support, and third while wearing MobiLead. The EMG provides insight into two different muscular parameters: the root mean square (RMS) and the median frequency (MF). The RMS measures the muscle activity, where a higher muscle RMS indicates increased muscle activity. Comparisons show how movements change through the three different states, such as more support generates more or less movement of the relevant muscle groups. The MF is used to determine the muscular fatigue. A lower MF for a certain muscle at the end of the procedure indicates more fatigue. To determine if MobiLead reduces fatigue relative to the standard lead garment convention, this study compares the differences in RMS and MF values.

These tests assessed the muscles that are often strained by wearing standard, heavy lead garments, particularly the upper trapezius and erector spinae muscles. For testing, three subjects were tested with two EMG nodes, one on each upper trapezius. One subject was also measured with four nodes, two on the upper trapezius, and two on the erector spinae. Previous studies about back fatigue while carrying a back-mounted load also measured EMG signals for these muscle groups to measure muscle fatigue. [4]

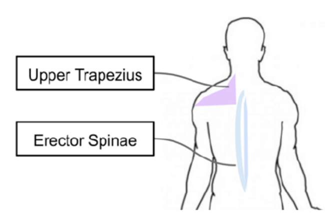

Figure 3. The muscles studied were the upper trapezius and erector spinae

In order to isolate muscle groups and avoid interference from nearby muscles, calibration was conducted on each subject to isolate muscles by placing the node around the muscle body until the signal was clear and easy to discern. Each session lasted for 30 minutes, and the subjects stood at a desk on their laptop or using a notebook for the duration of the time. Any sudden spikes in data are attributed to an abnormal movement and generally disregarded for the test. Upon conclusion of the tests, analysis of the data began with removing offsets. Since the four subjects performed the session over two or three different sessions, the node placement, existing energy/fatigue level of the subject, and other external parameters may have varied slightly over the sessions.

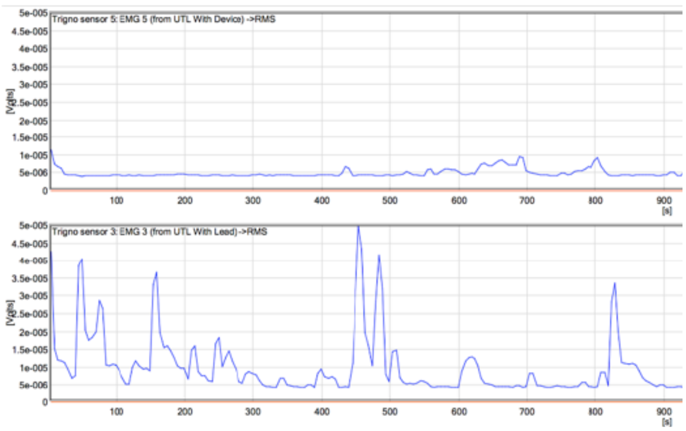

Figure 4. Root mean square of data collected with EMG sensors from an upper left trapezius muscle. Top: Trial with MobiLead system, Bottom: Trial with standard lead garment.

To standardize the EMG results and remove data offsets, the mean was subtracted from each signal before performing MF and RMS analysis. EMG data in Fig. 4 shows upper trapezius muscle through the RMS response to the two loads. The top plot shows the muscular response while wearing MobiLead, and the bottom plot is the response while wearing normal lead. Since higher RMS indicates more muscle activity and work done by the muscle, the bottom plot shows higher values than the top plot and data was also taken while not wearing a device, as a control. Fig. 4 data shows that the signal while wearing the lead vest remains between $3x10^{-5}$ V to $4x10^{-5}$ V while the MobiLead and no lead signals are on average under $1x10^{-5}$ V. Similar trends in muscle response between the MobiLead and no lead trials indicates that the use of MobiLead could significantly reduce muscle fatigue over time. This should be further validated by controlled studies with a statistically significant number of trials.

This preliminary EMG data validates the MobiLead design, and indicates that MobiLead does reduces muscle activity and use compared to wearing standard lead attire. Since a lower median frequency represents higher muscle fatigue, it is interesting to observe trends in these plots over time. A higher median frequency is better, because it indicates the muscle is less fatigued. While not wearing lead attire, the median frequency peaks remains approximately the same over time, staying around 65Hz. While wearing MobiLead, the MF peaks similarly stays the same around 65Hz. However, with the standard lead garment, there is a distinct decrease in MF over time.

INTERPRETATION

Validated by preliminatry tests, MobiLead fully removes the load of the lead skirt off the surgeon and redistributes the remaining load from the vest to the hips. In doing so, MobiLead reduces the risk of fatigue and longitudinal injury for the surgeon. MobiLead is a unique design due to its four-wheel structure, ergonomic design, and manipulation of distributed loads. The wheel placement allows for an unobstructed bottom frame which completely removes the load of the lead skirt off body. These elements created a stable design that fit a wide range of body types while still reducing the possibility of discomfort and fatigue for the user.

Comparing the RMS and MF data of the targeted muscle groups demonstrated positive preliminary EMG test results that show the expected increasing fatigue trend for each muscle group across all test groups. The MobiLead test group showed reduced muscle activity and fatigue over time compared to the test group wearing the standard lead garment.

Therefore, MobiLead is a novel, mobile lead garment support solution with potential for further testing and commercialization. The design was validated qualitatively through ergonomic dimensioning, surgeon feedback, and initial EMG data collection and analysis. This corroborative evidence shows that MobiLead reduces the muscle fatigue and load on the upper trapezius and lower back muscles, and meets all the specifications.

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