DESIGN OPTIMIZATION OF AN ERGONOMIC LEAD GARMENT

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Abstract

The lead garment is the most popular protective equipment used by medical teams to protect against the side effects of radiation. Many alternatives have been made to the garment however the lead garment is the most popular as it absorbs almost all of the radiation and allows for greater functionality and movement within an operating room. However, the garment weighs around 20 pounds causing a significant amount of ergonomic challenges for the medical teams who wear them, sometimes up to 10 hours a day. This has caused significant musculoskeletal injuries as a significant amount of weight and pressure is being applied to the shoulders and lower back. Therefore, the aim of this study was to design a novel hook brace that could be worn underneath the garment to lift off the pressure and weight from the shoulders and redistribute it more proportionately to help alleviate the pain. Input was gathered from medical professionals at the University of Virginia Hospital to establish design needs allowing a mock prototype to be completed and pressure sensor testing to occur. Due to unfortunate circumstances in person testing was unable to be completed and instead pressure sensor simulation testing was performed through Computer Aided Design (CAD). The results indicated that this device would help alleviate pain and redistribute weight however, further research needs to be conducted in the form of in person testing to account for variables that cannot be provided for via a simulation.

Keywords: lead garment, ergonomic, CAD, musculoskeletal injuries, pressure

Introduction

A lead garment is protective gear used by radiographers, surgeons, and medical teams to protect against the side effects of radiation. It is the main item of protective clothing as it can absorb around 95% of the radiation[1-3]. As surgery is moving towards more minimally invasive procedures[4] the use of x-rays and need for protective clothing has gone up with increased radiation exposure. The main issue with the garment is that it weighs up to 20 pounds and can apply a load of approximately 300 pounds per square inch on intervertebral disk spaces[5]. These health professionals wear these garments anywhere from 4 to 10 hours a day while performing operations causing a significant amount of discomfort and fatigue. Research has shown that surgeons are at moderate risk of occupational injury throughout their careers because of workplace devices and circumstances[6]. Health staff experience more low back pain than other occupations[7] and a significant amount miss work because of this pain[8]. A recent study was conducted to determine the amount of pain experienced by Mayo Clinic employees in the cardiology and radiology departments. As seen in Figure 1, the study concluded that most work-related pain was experienced by technicians at 66%, followed by registered nurses at 60%, attending physicians at 40%, and trainees at 19%[9]. The study showed that healthcare personnel who worked in procedures that utilize radiation experienced more work-related pain (54.5%) than their colleagues who did not (44.7%)[9]. In addition, out of all the employees that were surveyed 30% sought medical care due to work-related pain from lead garments and 16% developed short term and long term disabilities[9]. This device along with the fact that these medical teams are on their feet for most of the day causes a significant amount of stress on their shoulders and lower back leading to persistent pain as they progress through their careers.

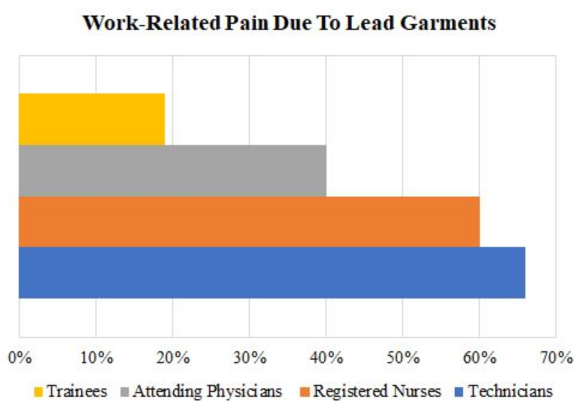

Fig. 1. Bar Graph of Work Related Pain Due to Lead Garments. The graph displays the work-related musculoskeletal pain among employees involved in procedures utilizing radiation, analyzed by job description (Orme et al., 2015).

One of the most recent innovations for protecting healthcare professionals against lead garment induced pain is the OrthoVest. The OrthoVest is a backpack-like apparatus worn under the lead garment that transfers the weight of the lead garment towards the hips in upright positions[10]. As seen in Figure 2, the OrthoVest covers both the front and back of the body and attaches to the body with an adjustable belt. Although the OrthoVest attempts to reduce weight on the shoulders and spine, it reduces the mobility for healthcare professionals. It has been seen to specifically restrict motion sidewards. The front structure also limits the effectiveness of the device for women. The almost flat front structure does not accommodate women in the field with larger breasts. While the OrthoVest is a good step in making healthcare professionals more comfortable, it is not an effective universal device for all healthcare professionals.

Although, alternatives have been made to the lead garment in the form of protective shields, zero-gravity machines and the Orthovest, these alternatives do not allow for free movement as the surgeon is attached to the contraption, have little to no protection around the neck area, are not easy to maneuver in an operating room, and do not allow for great functionality[11-12]. Moreover, the current alternatives do not function well for people of different heights, weights, gender, etc.

Therefore, the primary goal of this research was to design and test a universal novel hook brace to reduce orthopedic stress on surgeons and medical teams. Input was received from medical professionals at the University of Virginia Hospital to establish design constraints. Pressure sensor testing was completed and preliminary testing was completed with a mock prototype. A final model was submitted to be built by the University of Virginia Physics Machine Shop but due to unfortunate circumstances human volunteer testing was unable to be completed and instead pressure simulation testing was conducted through Autodesk Inventor and Computer Aided Design (CAD).

Fig. 2. Orthovest. The OrthoVest, a device currently on the market that is worn under lead garments to reduce pressure on neck, shoulder, and spine.

Results

Design Optimization

TABLE 1: Interview Data (n=19)	
Position	
CVT	36.8 (7)
RN	36.8 (7)
Fellow	26.3 (5)
Sex	
Male	42.1 (8)
Female	57.9 (11)
Average experience in years	5.92 ± 7.2
Average hours per week wearing lead garment	20.4 ± 4.4
Pain	68.4 (13)
Back pain	57.9 (11)
Neck pain	42.1 (8)
Shoulder pain	42.1 (8)

Table 1. Preliminary Interview Data. Analysis of iCore Questionnaire interviews with a sample size of n=19. Values are mean ± SD or % (n).

Preliminary Interviews at the University of Virginia Hospital

Overall 19 health professionals were interviewed using the iCore Questionnaire (Figure S1). Of the 19 interviewees 36.84% were cardiovascular technicians (CVT), 36.84% were registered nurses (RN), and 26.31% were fellows. The average number of hours worked per week by these professionals was 20.4 with a standard deviation of 4.4 hours. Of the participants 42.1% were male and 57.9% were female. Overall pain, back pain, neck pain, and shoulder pain were assessed through the questions as well as their thoughts on the current challenges and limitations of the lead garment. Many of the participants stated that it was difficult to move around, especially bend down if they needed to grab something. They also stated that the weight made it difficult to move and caused a significant amount of pain as can be seen from the (Table 1). Overall 68.42% of all the participants claimed that the device caused pain with 57.89% of that pain coming from the back, 42.10% from the neck, and 42.10% from the shoulders. Some of the major challenges and limitations associated with the garment were weight, difficulty to get low, and mobility. The results from the preliminary interviews established the design needs for the novel hook brace in Figure 3. In order to test the feasibility of the design, a test prototype (Figure 4) was also made out of hangers and a belt.

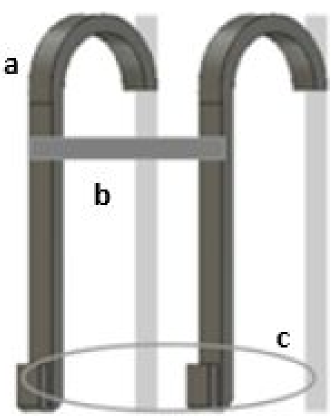

Fig. 3. CAD Design of Hook Brace. The two hooks (a) sit under the vest with a band (b) at the top to keep the hooks in place and an elastic belt (c) at the waist to secure it to the body.


Fig. 4. Test Prototype. The test prototype was created out of a hanger and a belt to see test feasibility of the design.

Pressure Testing

Pressure Sensor Testing with Standard Lead Garment

Pressure sensor testing was conducted to establish a baseline for the standard lead garment. The garment was worn for a total of 30 minutes with measurements taken at 5 minute intervals to assess how the amount of pressure felt on physicians shoulders changes as time progresses. The results displayed in Table 2 below, indicated that in one case the pressure increased as time went on. For the first case pressure for the right shoulder went from 9 mmHg to 15 mmHg and for the left shoulder went from 10 mmHg to 20 mmHg. For the second case it stayed relatively stable starting at 15 mmHg and 17 mmHg for the right and left shoulder respectively and ending at 15 mmHg and 16 mmHg. While only one run was able to be completed the results did show that the pressure felt was increased slightly. While 9 mmHg might not seem like a lot of pressure, after wearing the device for up to 10 hours a day multiple times a week can cause significant injuries to the professional[13-20]. That is a significant amount of weight to bear down on an individual's shoulders and spine for a prolonged period of time.

	Briana (in mmHg)		Rohni (in mmHg)	
Runs	Pressure R	Pressure L	Pressure R	Pressure L
1	9	10	15	17
2	11	12	12	15
3	12	13	12	12
4	16	18	11	14
5	15	18	12	14
6	15	20	15	16

Table 2. Preliminary Pressure Sensor Data. R denoting pressure sensor placed on the right shoulder and L denoting pressure sensor placed on the left shoulder. Values in mmHg.

<u>CAD Pressure Simulation Testing</u>

As testing was not able to be completed of the design, mock human model pressure simulation testing was completed. Originally prototype testing was going to include mannequin testing but as the project progressed this was cut out due to time constraints. This along with the fact that Autodesk Fusion 360 does not have any material properties that could mimic the human body, the mock human model was chosen to be made of the material polyethylene which is used to make mannequins. As can be seen in Figure 5, runs were conducted to determine pressure experienced. The pressure measurements used were the ones established by the pressure sensor testing. The pressure measurements were applied to the mock human model in the same location as the pressure sensors were in human testing. As can be seen in Figure 5, this caused a significant amount of weight to be experienced on the individual's shoulders. There is also an outline of the body behind it indicating where the model was relating to how much pressure and weight was brought down on the shoulders. As can be seen the pressure from the standard lead garment negatively impacted the mannequin mock model as the shoulders sagged immensely and the peak in color where the pressure was applied. The colors indicate how extreme the pressure would be with light blue as the least amount of pain and the yellow/red as the most and the dark blue as no effect. As can be seen there is a significant amount of yellow/red coloring around the shoulders of the mannequin model indicating the significant amounts of pain that is experienced by medical professionals. The hook design was then tested by placing the CAD design of the hook on the mannequin model as would be on a real human with a belt to secure it at the waist and a band to secure it at the shoulders. Pressure was then applied in the same manner. As can be seen there was little to no weight on the models shoulder with the hook design indicating that the design would be sustainable and effective. However, the design did bend significantly after a few runs indicating that it may have to be replaced frequently or altered depending on how often it was used.

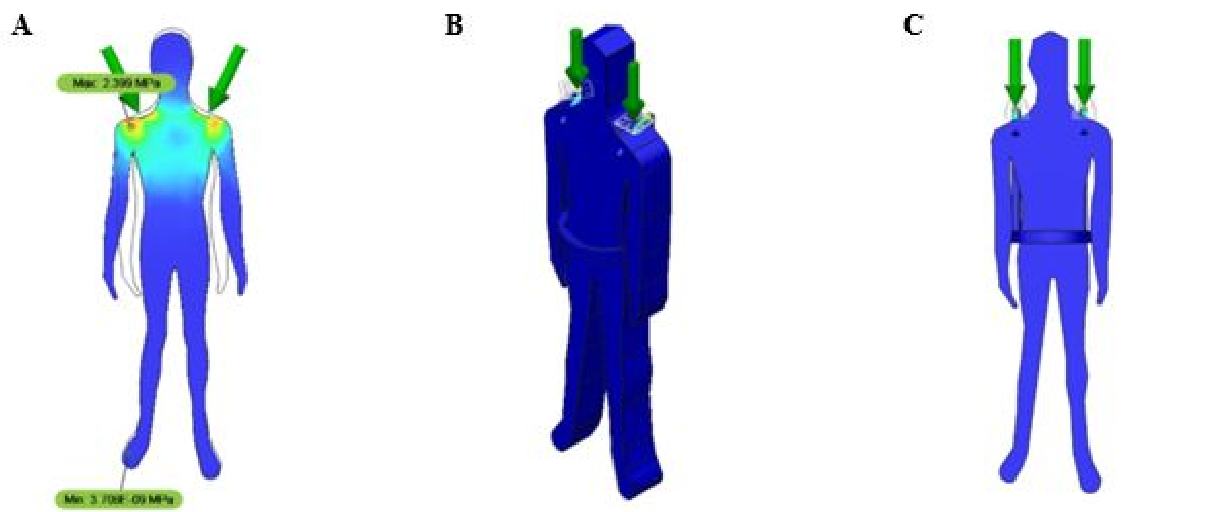

Fig. 5. CAD Pressure Simulation. (A) mimicked effect of regular lead garment (B) mimicked effects of regular lead garment on hook brace side view (C) mimicked effects of regular lead garment on hook brace front view

<u>Discussion</u>

There have been numerous studies linking the lead garment to interventionalist disc disease and orthopedic disease prevalent in cardiologists who use the device constantly[13-20]. Many have lost a significant time off from work and have had a higher incidence of skeletal complaints[13-20]. It has been shown that wearing and standing for extended periods each week has led to the prevalence of cervical spondylosis in interventional electrophysiologists with some having to switch careers because of the toll experienced by these garments[13-20]. For this reason it was imperative to have a novel solution that would alleviate the pain experienced but also still allow functionality.

While there are many alternatives to the lead garment, they do not provide adequately for medical professionals. The zero-gravity device is difficult to operate and maneuver in operating rooms and there is usually only room for one in each room not allowing every person in that room to be adequately protected. The same applies to lead shields. The Orthovest, as previously mentioned, makes sidewards motion more difficult. This novel device would allow for greater motion as it does not restrict individuals on the side. Also as it does not completely extend in the front it would be more comfortable for women to wear the device. Overall, this novel device adequately combats the problems with the previous alternatives and would serve as a better option than them.

The project also serves a greater purpose in its ability to advance the technical capability in the healthcare field of surgery and medicine by improving the functionality of an important medical device. With this improvement surgeons will be able to perform operations more effectively as a significant stress factor is reduced. It will allow increased mobility and functionality as the technical capability in clinical practice will increase significantly. Furthermore, the work done here will help develop methods and knowledge available for future use for improvement of other medical devices causing ergonomic issues, including the current alternatives to the garment. There are plenty of devices and situations in an operating room that cause a significant amount of ergonomic stress to medical teams and this research can progress the study creating a more favorable environment for those teams. Thus, this project serves as an important resource in the surgery field, especially the emerging minimally invasive surgery field. As the patient demand for these surgeries is increasing the research conducted will significantly impact that field. The expected results of this project are to lead to an improved quality of health and medical outcomes as well as improved performance and reduced health care costs.

Future Work

Future work includes conducting human testing, material testing and a potential cost analysis. While the CAD simulation testing was able to provide some feedback and evidence of the novel hook device working it cannot be ensured it will work properly without human testing. The simulation was not able to take into account gender, height, weight, previous injuries or medical conditions and comfortability. Without accounting for all of these aspects this design cannot be successful and sustainable. Another aspect that needs to be addressed is material used. Aluminum was originally chosen as it is a lightweight metal and the aim of this design was to reduce weight not add to it. However, simulation testing concluded that it might not be as sustainable for long term use as it bent after a couple of runs. This leads to the cost benefit analysis that would have to be conducted of whether the device would have to be replaced often if aluminum was used and if that would be better than using another material that wouldn't have to be replaced often but was heavier. While simulations served as a good alternative to find preliminary results, human testing and material testing need to be done to provide the best device.

Materials and Methods

Design Optimization

Preliminary Interviews at the University of Virginia Hospital

Interviews were conducted at the University of Virginia Hospital Electrophysiology (EP) Lab, in order to develop a better understanding of current limitations of the standard lead garment. An iCore Questionnaire (Figure S1) was used to conduct interviews with 19 health professionals (7 cardiovascular technicians, 7 registered nurses, and 5 cardiovascular fellows). Relevant questions from the iCore Questionnaire include but not limited to: On average how many hours do you wear the lead garment per month? Have you experienced an increased amount of lower back pain since you started wearing this device? Have you experienced an increased amount of neck and shoulder pain since you started wearing this device? What are the major challenges and limitations associated with this device? This questionnaire established design constraints and needs.

CAD Design

A CAD design as seen in Figure 3 was created from the test prototype to allow the Physics Machine shop to build the design. Measurements for length, curvature of hook, and size were obtained from the test prototype. Aluminum was used as the material as this was the most lightweight metal possible to use.

Test Prototype

A test prototype was created from hangers and a belt as seen in Figure 4. This prototype was created to test the feasibility of the hook design and preliminary testing was conducted to determine comfortability. The prototype was worn underneath a standard lead garment and results indicated that it would be able to sustain the weight and allow for adequate motion and function.

Pressure Testing

Pressure Sensor Testing

Pressure sensor testing was conducted with the standard lead garment to establish a baseline and compare if the novel hook design had in fact alleviated pressure from medical professionals shoulders. Pressure sensors were placed on the right and left shoulder with the lead garment worn overtop. The garment was worn for a total of 30 minutes with pressure sensor readings taken every 5 minutes. Pressure measured in mmHg.

CAD Pressure Simulation Testing

A mock mannequin human body model was created in CAD to test the previously made CAD design of the hook since in person testing could not take place. The human model material was made of polyethylene to mimic the materials used to make mannequins. The CAD hook design was placed on the human body model’s shoulders and pressure was applied to determine if the design could sustain the weight. Pressure measurements were taken from the pressure sensor testing runs.

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Supplement

Supplementary Figure 1.

Lead Garment Questionnaire

1. What is your name and role? And how much experience (number of years or months) do you have working in this occupation?
2. On average how many hours do you wear the lead garment per month? Per week?
3. How long are the surgeries in which you wear this device?
4. Have you experienced an increased amount of lower back pain since you started wearing this device?
5. Have you experienced an increased amount of neck and shoulder pain since you started wearing this device?
6. Have you had to receive medical treatment due to orthopedic pain from the device?
7. What are the major challenges and limitations associated with this device?
8. How do you think the current design can be improved?
9. What are your thoughts on current alternatives such as the Zero-Gravity contraption and the Lead Box? Have you used them?
10. In your opinion does this device operate to its performance standards and are you content with it? Does it perform the functions it needs to?
11. What is your strategy to reduce the impact of weight felt during surgery?
12. Does the garment affect your ability to accurately perform surgeries?
13. Do you ever have to pause surgery to readjust or reattach the device?
14. How frequently do you have to get a new lead garment?
15. How do you store the lead garment?