A multifaceted approach to evaluating surgical exoskeletons

by

Joseph Yun-Ming Kim

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Susan Hallbeck
Kris De Brabanter

The student author, whose presentation of the scholarship herein was approved by the program of study committee, is solely responsible for the content of this thesis. The Graduate College will ensure this thesis is globally accessible and will not permit alterations after a degree is conferred.

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DEDICATION

My academic degrees at Iowa State and this thesis are dedicated to 할아버지(Grandpa) and my other three grandparents. 할아버지, I was never able to say thank you for all that you did, and I wish you were here to see me graduate; I know you're looking down happy for all of us, and I hope you knew how grateful all of us were for you. To all my grandparents, thank you for the incredible sacrifices you all made your entire lives. Your children, grandchildren, and everyone else who crossed your paths are so much better because of it. We owe you everything and are so grateful for all that you did.

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我在爱荷华州获得的学位和这篇论文献给了할아버지（爷爷）和我的其他三位祖父母。 할아버지，**我一直无法**对你所做的一切表示感谢，但我希望你能在这里看到我毕业； **我知道您**为我们所有人感到高兴，我希望您知道我们所有人对您的感激之情。 **致我所有的祖父母**，**感**谢你们一生做出的令人难以置信的牺牲。 **你的孩子、**孙子和所有遇到你的人都因此变得更好。 **我**们欠你一切，非常感谢你所做的一切。

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at Mayo Clinic; without her, I would not be where I am today, and I am incredibly grateful for her and all that she has done for me and countless others.

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ABSTRACT

Surgeons are particularly susceptible to developing musculoskeletal disorders due to long hours and awkward postures. There have been many interventions suggested, but one of the most promising is the application of exoskeletons to the operating room. Exoskeletons are worn by users and will support the body to theoretically decrease the fatigue and muscle activation experienced by users. There have been a few studies attempting to study the effectiveness of exoskeletons and how they might be applied to surgeons. As a result, a literature review was conducted, which analyzed previous studies of surgical exoskeletons. These studies were then categorized according to various aspects, such as the type of exoskeleton, purpose, and outcomes studied, and patterns were compared to one another. It noted that active exoskeletons are almost exclusively focused on performance augmentation exoskeletons, while passive exoskeletons are almost entirely interested in ergonomic exoskeletons. Despite this compartmentalization, to make the strongest case for exoskeletons, if the next step of implementation is to be achieved, multiple aspects from each primary category must be considered. A recommendation at the end of Chapter 2 was made to test performance augmentation, ergonomic, and usability features at the very least.

After proposing this multifaceted approach to evaluating exoskeletons, a study was conducted consisting of eight participants who performed twelve trials by standing in a static posture for twenty minutes each. Activation of the exoskeleton (being in tension or not), material choice, and posture were all analyzed to determine if any significant effects existed. Muscle activations of the splenius capitis, splenius cervicis, and erector spinae were recorded using EMGs, and participants recorded their levels of pain, opinions about the exoskeleton and type of material that was being used, and performed cognitive and dexterity tests. It was found that when

the exoskeleton was activated, it could decrease changes in pain and the percent muscle activation and improve perceptions of the exoskeleton. Additionally, by selecting high-density foam, the softest material, there was a decrease in the change in overall pain. Cognitive and dexterity tests did not have any statistically significant differences, regardless of the factors involved.

CHAPTER 1. GENERAL INTRODUCTION

The development of musculoskeletal disorders (MSDs) can be attributed to a variety of factors, such as repetitive movements or awkward postures held for extended periods. Surgeons and surgical staff in the operating room are susceptible to developing MSDs, or at least their symptoms, due to the awkward postures they have to hold. As a result, human factors and ergonomics (HFE) researchers have attempted to create potential solutions to reduce the risk of developing these MSDs. One potential mitigation that has become increasingly popular in manufacturing industries has been the exoskeleton.

Exoskeletons are worn externally and provide support in different ways, such as by improving their performances or assisting body parts, potentially reducing the possibility of developing an MSD. However, the potential implementation of exoskeletons into the operating room is still fairly preliminary, and many aspects are still yet to be studied. This paper addresses this in a two-part approach. First, in Chapter 2, a literature review was performed on surgical exoskeletons to identify potential gaps. During the literature review, exoskeletons were categorized based on their type, purpose, and study design, and patterns were studied. From there, a multifaceted approach that may create a stronger argument for why exoskeletons should be implemented into the OR was suggested.

In the second part of this paper, found in Chapter 3, the multifaceted approach was utilized in an experiment testing a head and neck exoskeleton. Potential performance augmentation characteristics were considered by having participants perform cognitive and dexterity tests, ergonomic interventions were assessed by observing changes in participants' pain levels, changes in muscle activations using electromyography (EMG), and subjective impression of the usefulness of the exoskeleton, and the usability was assessed by optimizing the material

that was used as well as asking questions regarding the features that were liked or not in the exoskeleton. By assessing these three factors simultaneously, it follows the framework suggested by the literature review and assesses whether this framework is more powerful than the traditional methods explicitly focused on just one aspect of the exoskeleton.

CHAPTER 2. A MULTIFACETED ARGUMENT FOR THE IMPLEMENTATION OF SURGICAL EXOSKELETON: A LITERATURE REVIEW

Joseph Kim*, Richard Stone*, Susan Hallbeck*+, Hamid Norasi*+

* Department of Industrial and Manufacturing Systems Engineering, Iowa State University

+ Robert D. and Patricia E. Kern Center for the Science of Healthcare Delivery Division of Healthcare Delivery Research Mayo Clinic Rochester, MN

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Abstract

Surgeons are a class of workers susceptible to developing musculoskeletal disorders. One potential mitigation is the exoskeleton, a wearable device that assists its user. Exoskeletons can either be passive (not electrically powered) or active (electrically powered), and surgical exoskeletons are designed for training, performance augmentation, or as an ergonomic intervention. A literature review was performed on exoskeletons designed for surgical staff; 16 articles were identified and then categorized based on their purposes, exoskeleton types, and the types of studies performed. Exoskeleton type was closely associated with the purpose, as passive exoskeletons almost exclusively included ergonomic exoskeletons (7 of 8 studies), while active exoskeletons almost exclusively focused on performance augmentation (6 of 7 studies). This compartmentalization was seen in the outcomes, as few ergonomic exoskeletons evaluated potential performance augmentation outcomes. Multiple outcomes should be assessed to create the strongest argument for the implementation of exoskeletons, namely, usability, ergonomic evaluations, and performance augmentation.

[1] This chapter is currently a work in progress. It may differ in significant ways from the published version.

Introduction

Human factors and ergonomics (HFE), or the study and improvement of how humans work, is a relatively modern field; the scientific approach to HFE became increasingly popular during the early 20th century in industry, especially with the start of World War II (Meister, 1999). Although HFE was originally frequently applied to the industrial setting, it has since been applied to less conventional fields, such as agriculture (Fales et al., 2022) and healthcare (Berguer, 1999; Catanzarite et al., 2018; Meltzer et al., 2020; Norasi et al., 2021; Van Det et al., 2009). Regardless, the goal is the same: improve human work by making it safer, more productive, and overall better.

Since 2000, there has been an influx in the study of HFE in the healthcare sector (Hignett et al., 2013), especially regarding the study of surgery, and for good reasons. Studies have shown that surgeons are at an increased risk of developing musculoskeletal disorders (MSDs, which can lead to chronic conditions, early retirement, and a worse quality of life. These conditions present as fatigue, pain, discomfort, and soreness, notably in the back and the neck. In fact, symptoms of MSDs in surgeons have been reported between 66% to 94% of surgeons performing open surgeries and many other types of surgeries having similar proportions of surgeons who also suffer from this pain (Catanzarite et al., 2018). Similar numbers have been reported in multiple publications, which have also observed that these MSDs can be spread throughout the body, namely in the back, neck, shoulders, and arms (Janki et al., 2017; Stucky et al., 2018), resulting in pain throughout these body parts. Surgeons who suffer from this pain have also reported that it can be experienced regularly, including while operating, causing some to be forced to take breaks during surgeries (Soueid et al., 2010). Furthermore, previous research demonstrated that fatigue could adversely affect surgeons' psychomotor and cognitive skills and increase the

likelihood of committing a medical error (Gerdes et al., 2008; Sugden et al., 2012). Even when considering pain itself and its impacts on any human, there are negative impacts on cognitive performances that will arise as a result (Keogh et al., 2013). In considering all of this, the need to alleviate this not only to improve surgeons' lives but also for the safety of the patient becomes obvious.

HFE has begun addressing this issue with techniques including incorporating microbreaks (Coleman Wood et al., 2018; Hallbeck et al., 2017; Park et al., 2017; Sarker et al., 2021) and other interventions and evaluations to decrease the risk of developing these MSDs (Van Veelen et al., 2004; Wee et al., 2020). One intervention of particular interest has been exoskeletons. Exoskeletons are a type of equipment that can be used to support or augment a user's capabilities. They can be found in two forms: active or passive. Active exoskeletons utilize a continuous supply of electrical power, while passive exoskeletons are not electrically powered but instead help capture and redirect users' energy through the use of components such as hydraulics (Matthew et al., 2015).

Exoskeletons can be further categorized according to their functionality as described by Perry et al., who broke their functionality into four categories: physiotherapy (rehabilitation), assistive devices (increasing strength, stability, support, etc.), haptic devices (improving sensations), or master devices (robotic controllers) (Perry et al., 2007). In current exoskeleton research, there is an abundance of literature focused on physiotherapy-focused exoskeletons (Heo et al., 2012; Lo & Xie, 2012; Matthew et al., 2015; Shi et al., 2019), but they often are designed for patients and are not necessarily relevant to the surgical setting; exoskeletons designed for use in the operating room or a surgical setting (subsequently referred to as "surgical exoskeletons") have focused primarily on the other three categories. Of these remaining three

categories, the HFE community has been especially interested in assistive exoskeletons to decrease the risks of MSDs, subsequently referred to as “ergonomic exoskeletons,” by allowing them to hold their current awkward and risky postures for long periods of time while still having continuous support. If intraoperatively feasible, these exoskeletons could be a promising solution to the ergonomic crisis that surgeons face.

Assistive exoskeletons are not confined solely to reducing the risks of MSDs; some exoskeletons’ end goal is “performance augmentation,” which means improving surgeons’ performances, leading to improved surgeries and better patient outcomes. Haptic and master device exoskeletons are also associated with this category. These performance augmentation exoskeletons share the same end user as ergonomic exoskeletons: surgeons in the OR. However, both categories differ in their primary benefactors, as performance augmentation exoskeletons should improve patients’ outcomes while ergonomic exoskeletons target the surgeon. These differences are manifested in the methodologies and the outcomes that are observed throughout each study. The differences are not always clear-cut, though, as performance augmentation and ergonomic improvements are not mutually exclusive; this leads to a compelling gap. Instead of being limited by their own methods, other outcomes and methodologies can be synthesized to adapt the best aspects of various categories of studies.

This paper analyzes the existing literature on surgical exoskeletons, mainly focusing on passive and active ergonomic exoskeletons, by categorizing exoskeletons based on the body parts being supported, exoskeleton type (passive or active), purpose (performance augmentation, ergonomics, or training), and type of study performed and their respective methodologies. By performing this analysis, trends in different types of exoskeletons and the outcomes they study can be seen. Popular trends will reveal how surgical exoskeletons in each category can be

especially beneficial, but the inverse will also be true; gaps in the current literature will be revealed as certain categories may not have the same outcomes measured in other types of exoskeletons. These gaps will allow the researchers to suggest novel outcomes that can be added to future exoskeleton studies. Ultimately, there is a particular focus on assistive, ergonomic exoskeletons to identify potential improvements and novel outcomes that may help implement and adopt surgical exoskeletons in the OR. It is hypothesized that there will be a significant gap between the exoskeleton type with purpose, and more work should be done to integrate a wider range of outcomes and not focus solely on either ergonomics or performance augmentation.

Methods

Before searching for literature, criteria were created to determine the papers that should be included. Studies were included/excluded based on the following criteria:

1. Literature was limited to peer-reviewed journal articles and conference proceedings/papers.
2. Theoretical/conceptual exoskeleton creations or models, trials testing human subjects using the exoskeleton, and literature reviews were all included; however, studies must evaluate the use of exoskeletons.
3. Exoskeletons must be designed for use in the operating room (real or simulated) and could be used by any team member in the operating room (attending surgeons, surgical residents, nurses, technicians, etc.).
4. Exoskeletons focused on physiotherapy or that were designed for patients and not healthcare providers were excluded.

5. Master devices were generally excluded unless the exoskeleton was meant to be worn/equipped by a human subject. Including these devices would have meant including many surgical robots, which is outside of the scope of this paper.
6. Studies must be available in English.

Keywords and phrases were used to find various sources. The primary keyword used was "exoskeleton," which was then combined with either the word "surgery/surgical," "healthcare," or "ergonomics" to find relevant sources. For example, one search was "surgical exoskeletons," while another was "exoskeleton healthcare." Each of these combinations of words was used and exhaustively investigated. Databases including Google Scholar, PubMed, and Science Direct; Applied Ergonomics, Human Factors, HFES, the Journal of Safety, and IISE Occupational Ergonomics and Human Factors were a few primary sources utilized. The researchers then read titles and abstracts from the keyword searches, and appropriate sources that met all criteria were included. Additionally, relevant papers' citations or other papers that cited said relevant papers were analyzed to determine if other appropriate studies were available.

One researcher was primarily responsible for reading through papers and determining whether the study was suitable to be included. After identifying relevant articles, they were categorized according to the exoskeleton type, purpose (ergonomics (reducing the risk of the staff developing MSDs), surgical training, or performance augmentation (improving surgeons' performances)), and the study type performed. Definitions of each category and their respective labels have been summarized in Table 1 below:

Table 1. Category Definitions

Category	Classification	Definition
Exoskeleton Type	Passive	Exoskeletons not powered by electricity
	Active	Exoskeletons powered by electricity
Study Design	Conceptual	Theoretical studies focused on developing or using models or simulations
	Human subjects research	Studies recruiting human participants to test an exoskeleton
	Literature review	Study analyzing past and present literature regarding surgical exoskeletons
Exoskeleton Purpose	Ergonomics	Exoskeletons designed to reduce the risk of developing MSDs
	Performance augmentation	Exoskeletons designed to improve surgical performances in the OR
	Training	Exoskeletons designed to improve surgical training of surgical students
Exoskeleton Functionality	Physiotherapy	Rehabilitation exoskeletons; excluded from this review
	Assistive devices	Improves a particular function of the user (strength, stability, support, etc.)
	Haptic devices	Improves sensations felt by the user
	Master devices	Controls a secondary source; wireless-controlled devices were excluded
Participant Type	Surgeons	Attending surgeons or surgical residents
	College students	Trials performed at a university primarily recruiting college students
	OR Staff	Healthcare providers other than the surgeon that help with surgeries

Results

Seventeen papers were identified that matched the criteria for inclusion, although one was excluded due to it being a conference proceeding with an incomplete data set later published in a journal; this led to a total of sixteen papers. Nine of those sixteen studied passive exoskeletons, while the remaining seven studied active exoskeletons. Regarding the exoskeletons' purposes, nine focused on ergonomics, seven on performance augmentation, and

the final study focused on surgical training. Ten of these studies were human subjects research trials, five were purely conceptual, and two were literature reviews. These categories can be seen in Figure 1 to Figure 3. A full breakdown of each source can also be seen in Table 2 below.

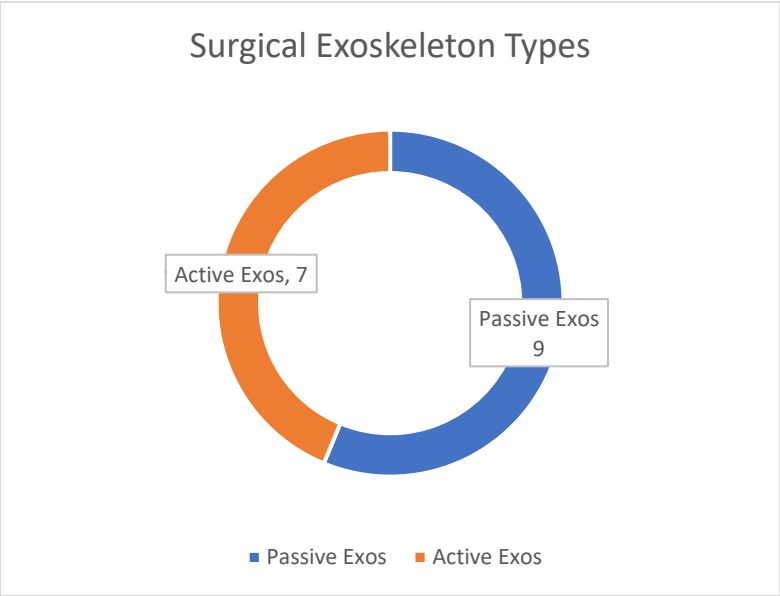

Figure 1. Ring Graph of Surgical Exoskeleton Types

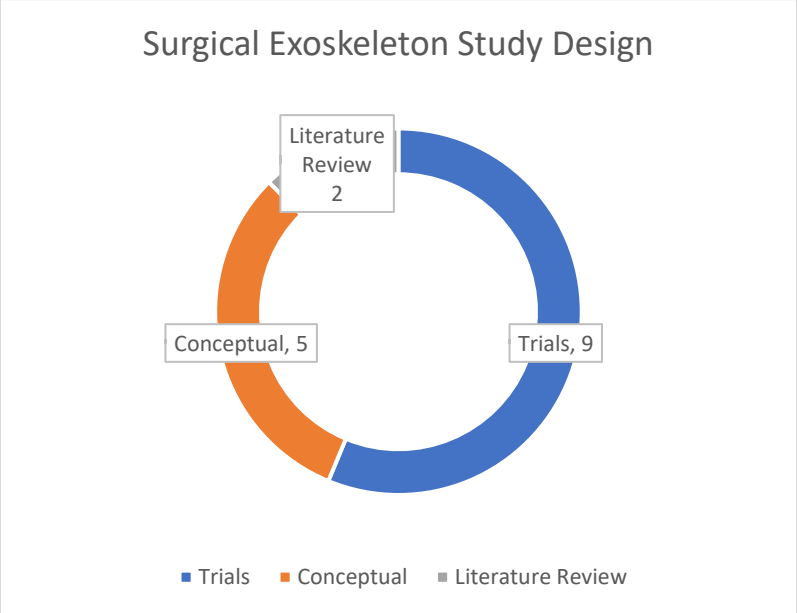

Figure 2. Ring Graph of Surgical Exoskeleton Study Design

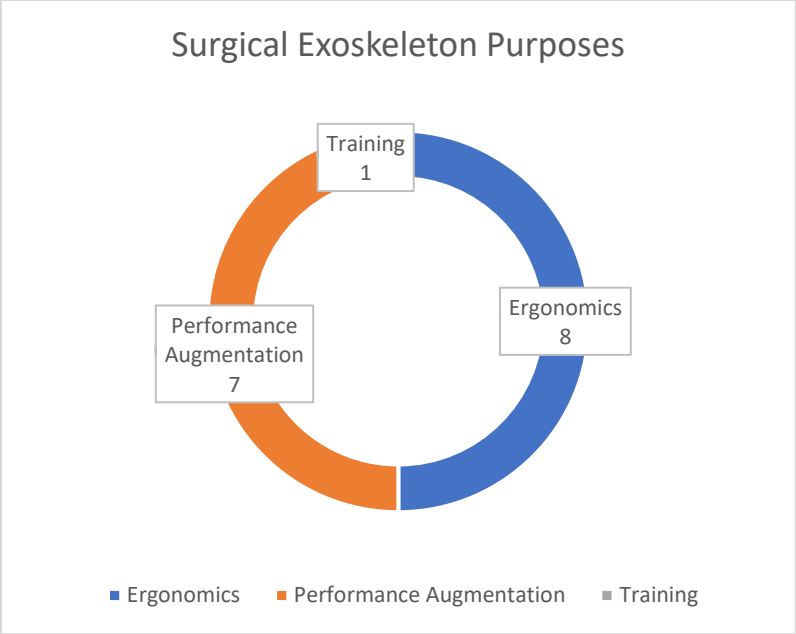

Figure 3. Ring Graph of Surgical Exoskeleton Purposes

These three classifications were then categorized relative to one another to determine how exoskeleton types affected their purpose and the research associated with said exoskeletons. Because the exoskeleton type (active or passive) was the broadest category, it was set as the primary level. This was followed by the study purpose and then the study type. Six of the seven active exoskeletons focused on performance augmentation and one on training. Of the six active performance augmentation exoskeletons, four were conceptual, one was a literature review, and the final was a physical trial. The active exoskeleton designed for training was also a human subject research trial. None of the active exoskeletons were focused on surgical ergonomics. On the passive exoskeleton side, eight of the nine passive exoskeletons focused on ergonomics, while the final exoskeleton was a conceptual design meant for performance augmentation. None of the passive exoskeletons focused on training. These results are shown in Figure 4.

Table 2. Classification of Literature on Surgical Exoskeletons

#	Citation	Exoskeleton Type	Purpose	Functionality	Study Design	Setting	Participant Type	Exoskeleton Body Part
1	(Albayrak et al., 2007)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	OR	Surgeons Residents	General body support
2	(Aoki et al., 2020)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	Lab	Surgeons	Arms
3	(Cha et al., 2020)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	Lab	OR Staff	Arms
4	(Goto, 2022)	Active Exoskeleton	Performance Augmentation	Assistive device	Literature Review	Online	Surgeons	Legs Arms
5	(Hessinger et al., 2015)	Active Exoskeleton	Performance Augmentation	Assistive device	Conceptual	Lab	Surgeons	Arms
6	(Jin & Agrawal, 2015)	Active Exoskeleton	Training	Assistive device	Trials	Lab	Unknown	Arms
7	(Liu et al., 2018)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	Lab OR	Residents/attendees	Arms
8	(Nishida et al., 2015)	Passive Exoskeleton	Performance Augmentation	Haptic device	Conceptual	Lab	Unknown	Hands
9	(Peter P. Pott et al., 2014)	Active Exoskeleton	Performance Augmentation	Assistive device	Trials	Lab	Surgeons	Arms
10	(Pott et al., 2014)	Active Exoskeleton	Performance Augmentation	Assistive device	Conceptual	Lab	Surgeons	Arms
11	(Santoso et al., 2022)	Passive Exoskeleton	Ergonomics	Assistive device	Literature Review	Online	Surgeons	Legs
12	(Secco & Tadesse, 2020)	Active Exoskeleton	Performance Augmentation	Haptic device	Conceptual	Lab	Surgeons	Hands
13	(Tetteh et al., 2022)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	Lab	College students	Neck Arms Lower back
14	(Tzemanaki et al., 2013)	Active Exoskeleton	Performance Augmentation	Master device	Conceptual	Lab	Surgeons	Hands
15	(Vorobyev et al., 2018)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	OR	Surgeons	Arms
16	(Wang et al., 2021)	Passive Exoskeleton	Ergonomics	Assistive device	Trials	OR	Surgeons	Lower back

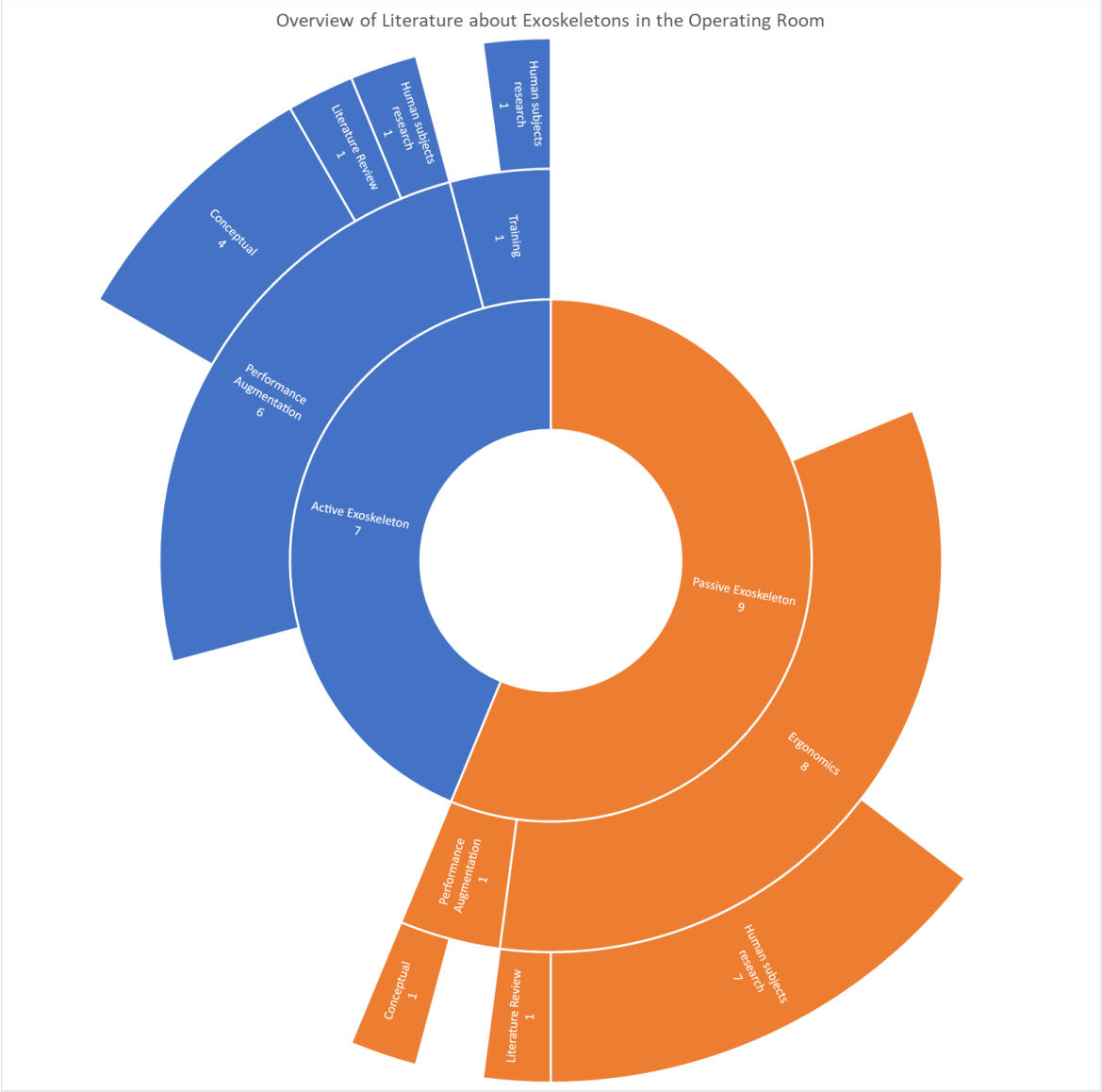

Figure 4. Breakdown of Literature Studying Exoskeletons in the OR

Another relevant categorization for surgical exoskeletons is the targeted body parts. A total of nineteen exoskeletons were studied, with six body parts supported. Arm support (from the wrist to the shoulders) was focused on in ten of the nineteen exoskeletons, which comprised more than half of the observed exoskeletons. Hands were the next largest category, with many exoskeletons focusing on the fingers, as three exoskeletons were observed. This was followed by

support of the lower back and legs with two exoskeletons each. The remaining two exoskeletons were designed as a general body support system that surgeons could lean on, while the final exoskeleton focused on supporting the head and the neck. Results from the entire literature review can be found in Figure 5 below.

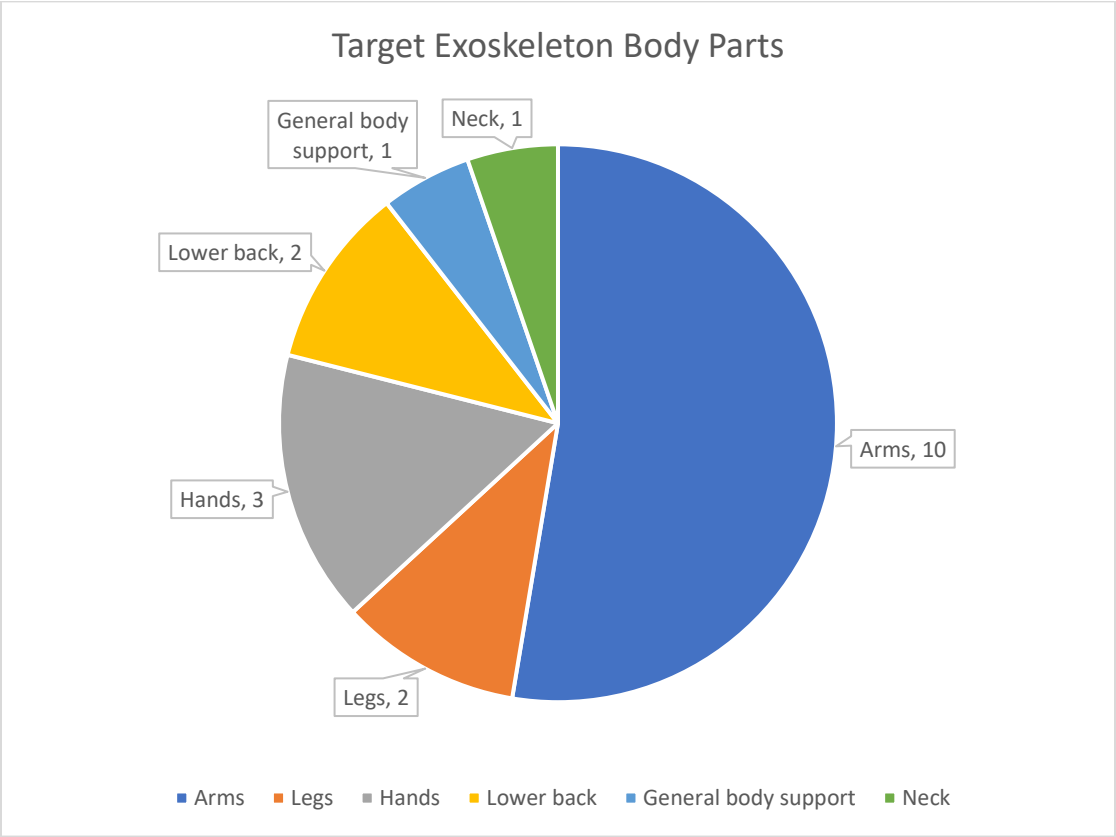

Figure 5. Pie Chart of All Exoskeletons and Their Target Body Parts

After observing the wide range of targeted body parts, the body parts were associated with the exoskeleton's purpose. Regardless of the purpose of the exoskeleton, the arms were a target feature as ergonomics, performance augmentation, and training included five, four, and one exoskeletons designed for the arms, respectively. Additionally, leg exoskeletons were observed in both ergonomics and performance augmentation, with one observed for each category. Past these two more general categories, though, were significant distinctions between

ergonomic and performance augmentation exoskeletons that could be found. Other body parts observed for ergonomic exoskeletons were two focused on the lower back, one on the neck, and one on general support, while performance augmentation had three exoskeletons targeting the hands and fingers. Complete results categorizing the target body part relative to exoskeletons' purposes can be seen in Figure 6f below.

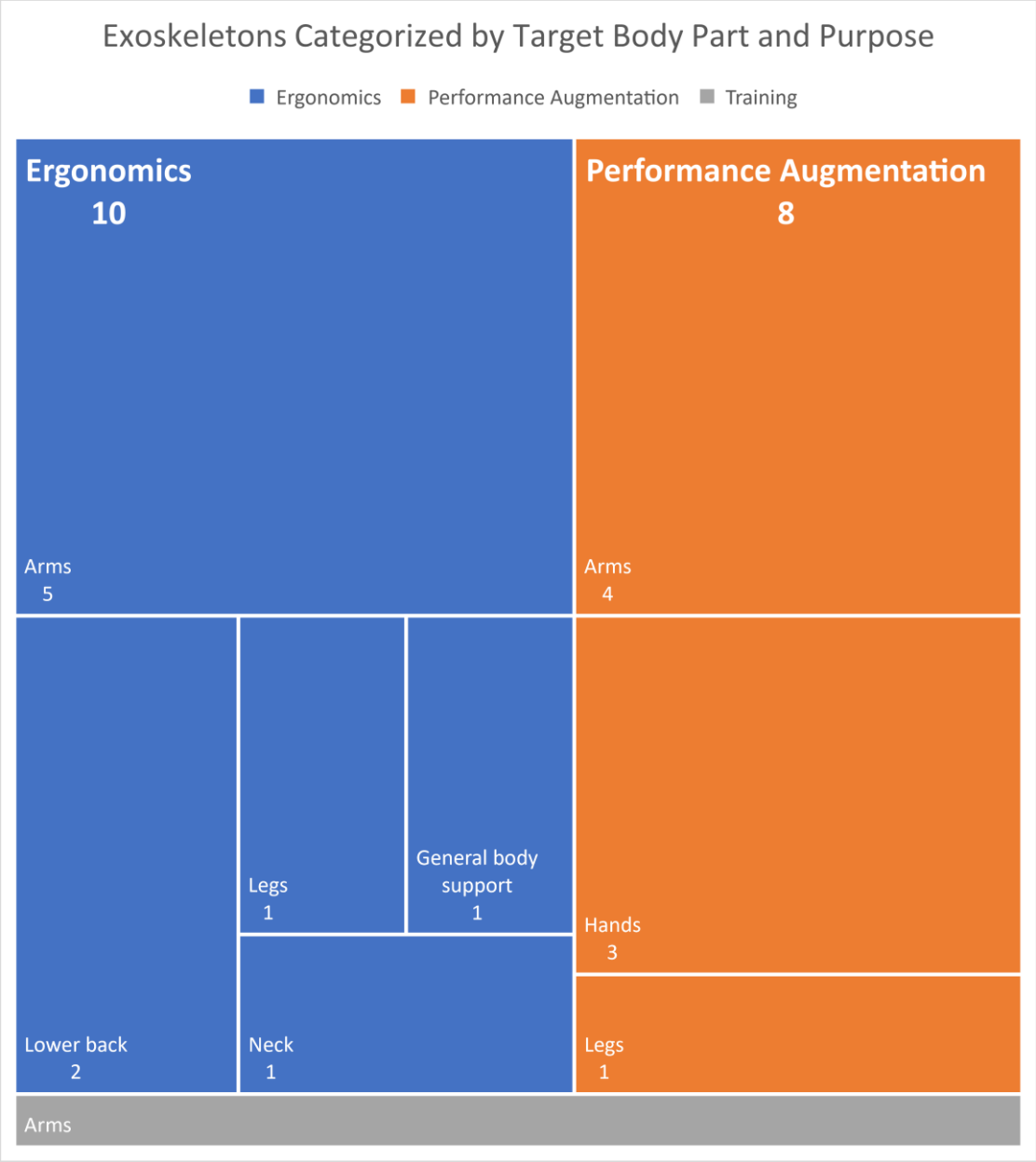

Figure 6. Exoskeletons' Target Body Parts Categorized Based on Purpose

In zooming out again to consider all of the studies of surgical exoskeletons, surgical ergonomics was exclusive to passive exoskeletons, and eight of the nine trials were human-subject research trials; this sub-categorization of studies was the largest group as it made up 50% (eight of sixteen) of the total studies. Due to this relatively large number of trials with human subjects, this group can be further analyzed with a focus on its measured outcomes. A breakdown of the dependent variables utilized in the exoskeleton trials can be seen in Figure 7. All outcomes evaluated in the studies of passive ergonomic exoskeletons are summarized in Table 3.

One of the most common outcomes observed was exoskeleton usability; six of seven passive human subject research trials asked about it. This included the use of surveys/questionnaires, interviews, or focus groups and could be as simple as merely asking users if they would use the exoskeleton again to as complex as inquiring about specific aspects that made the exoskeleton comfortable/useable. The extent of the questions asked will be further analyzed in a later section.

The next most commonly observed and similar subjective characteristic was the overall comfort of participants; five of the seven trials asked about participants' comfort levels. Questions were commonly asked in the questionnaires or during focus groups. This differed from usability as it focused explicitly on how comfortable or not the exoskeleton was and not necessarily on whether participants were willing to use the exoskeleton again.

On the objective side of data, two studies investigated users' dexterity with and without the exoskeleton. Each study typically employed a test that participants could use, such as the Purdue Pegboard Test used by Liu et al. (2018), and compared the levels before and after. Additionally, Liu et al. were the only ones to incorporate the Minnesota Dexterity Test and the

Fundamentals of Laparoscopic Surgery tests as measurable outcomes (2018). The only other dexterity test studied was by Aoki et al., who looked at the number of sutures placed while wearing the exoskeleton vs. not (2020).

The other objective evaluations were the use of surface electromyography (EMGs) and inertial measurement units (IMUs); three studies used EMGs, while two used IMUs. Most EMGs observed the muscle activation of the lower back (Albayrak et al., 2007; Tetteh et al., 2022), but it could also be found on the upper arms and depended on what kind of exoskeleton was used (Aoki et al., 2020). A notable objective exclusion was cognitive performances; none evaluated cognitive performances of the seven passive exoskeleton trials.

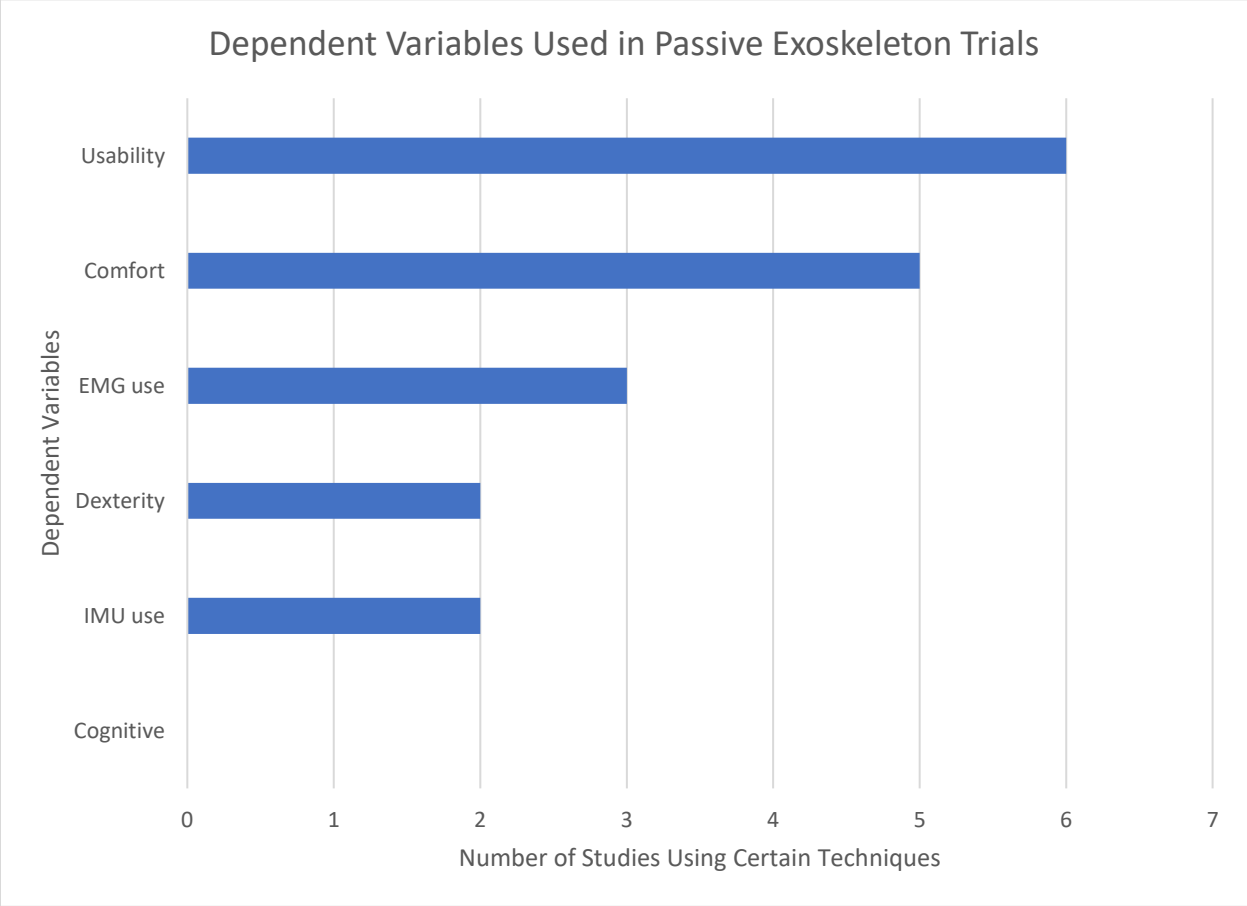

Figure 7. Distribution of Measured Outcomes in Passive Ergonomic Exoskeleton Studies

Table 3. Passive Ergonomic Exoskeleton Measured Outcomes

Citation	Participant Type	Surgery Type	# Participants	# Trials	Where	EMGs	Muscles	IMUs	Usability	Comfort	Cognitive	Dexterity	Other
(Albayrak et al., 2007)	Surgeons Residents	Open Laparoscopic	7	7	OR	Yes	Spine Semitendinosus Gastrocnemius	No	Yes	Yes	No	No	
(Aoki et al., 2020)	Surgeons	Laparoscopic	4	4	Lab	Yes	Deltoids	No	Yes	No	No	Yes	Heat
(Cha et al., 2020)	OR Staff	Laparoscopic	14	14	Lab	No	N/A	No	Yes	No	No	No	
(Liu et al., 2018)	Residents/attendees	Laparoscopic	20	20	Lab OR	No	N/A	No	Yes	Yes	No	Yes	
(Tetteh et al., 2022)	College students	Vascular/ Open	14	14	Lab	Yes	Lumbar erector spinae Lower thoracic erector spinae Medial deltoid Splenius capitis Iliac crest	Yes	No	Yes	No	No	
(Vorobyev et al., 2018)	Surgeons	Laparoscopic	16	39	OR	No	N/A	No	No	Yes	No	No	Time to fatigue
(Wang et al., 2021)	Surgeons	Vascular/ Open	3	11	OR	No	N/A	Yes	Yes	Yes	No	No	

Due to the large number of studies that investigated usability, it is possible to analyze the extent to which usability is investigated. Usability was defined as broadly as asking the users some form of the question, “would you use this device again in the future?” However, some studies emphasized usability more than others by administering questionnaires or asking more in-depth questions. One such questionnaire used in one of the studies was the System Usability Scale (SUS). Cha et al.’s study used this commonly utilized survey, where they paired these data with themes from interviews that allowed them to determine the factors necessary to make exoskeletons go from theory to implementation (2020). Focus groups were also utilized to help identify appropriate themes for implementation, with additional comments being considered for feedback.

Other than the SUS, the primary questions asked regarding usability were whether participants would want to use the exoskeleton in the future and an assessment of their ability to move around while using the exoskeleton; these questions were asked on questionnaires or during focus groups in three of the five studies that addressed usability. Questions about participants’ desire to use the exoskeleton were often general and typically asked, “would you use this exoskeleton in the future?” Movement capabilities were assessed in multiple ways, often asking about their range of motion or how free participants felt to move around, and could be found in three of the five passive exoskeleton human subject research trials.

Two of the five studies found the second most addressed questions surrounding exoskeleton usability and asked participants whether the exoskeleton interfered with work. Equipping the exoskeleton was assessed by asking about the pre-operative process and how easy/difficult it was. Interference with work asked participants if the exoskeleton affected the standard workflow relative to not wearing the exoskeleton. One of the two studies asked

participants about potential interference with their surgical instruments and the general workflow, including relative to how the other OR staff worked.

Along with the more commonly asked usability questions, there were a few noteworthy variables worth highlighting: equipping the exoskeleton, heat, safety, and simplicity. Each variable was only asked about once, with Cha et al. looking into the pre-operative process of equipping the exoskeleton (2020), Aoki et al. asking about the exoskeleton's breathability and heat (2020), and Albayrak et al. assessing the safety and simplicity of use (2007).

There were additional variables related to usability that were addressed in the questionnaires, but many were similar to metrics of comfort, such as fatigue, so they were not included in the analysis related to usability. As a caveat, the line between usability and comfort is commonly blurred, as those two metrics often go together; one cannot have an extremely uncomfortable device and still expect it to be usable. The variables mentioned here focused more on the questions asking about the qualities and perception of the exoskeleton second to participants' discomfort levels. Table 4 outlines the specific aspects of usability found in each of the passive ergonomic exoskeletons.

Table 4. Sources of Usability Features Addressed in Physical Trials for Passive Ergonomic Exoskeletons

Citation	**Want to use?**	**SUS**	**Other**
(Albayrak et al., 2007)	Yes	No	Movement restriction Safety Simplicity
(Aoki et al., 2020)	Yes	No	Workability while locked Workability while unlocked Physical burden on vs. off Heat
(Cha et al., 2020)	No	Yes	Impact on externalities Free movement Pre-operative process

Table 4 continued

Citation	Want to use?	SUS	Other
(Liu et al., 2018)	Yes	No	Discomfort Fatigue Hindrance Incorporation
(Tetteh et al., 2022)	No	No	
(Vorobyev et al., 2018)	Yes	No	
(Wang et al., 2021)	Yes	No	Interference Improve ability Range of motion Increase physical comfort Interfere with workflow Interfere with surgical equipment

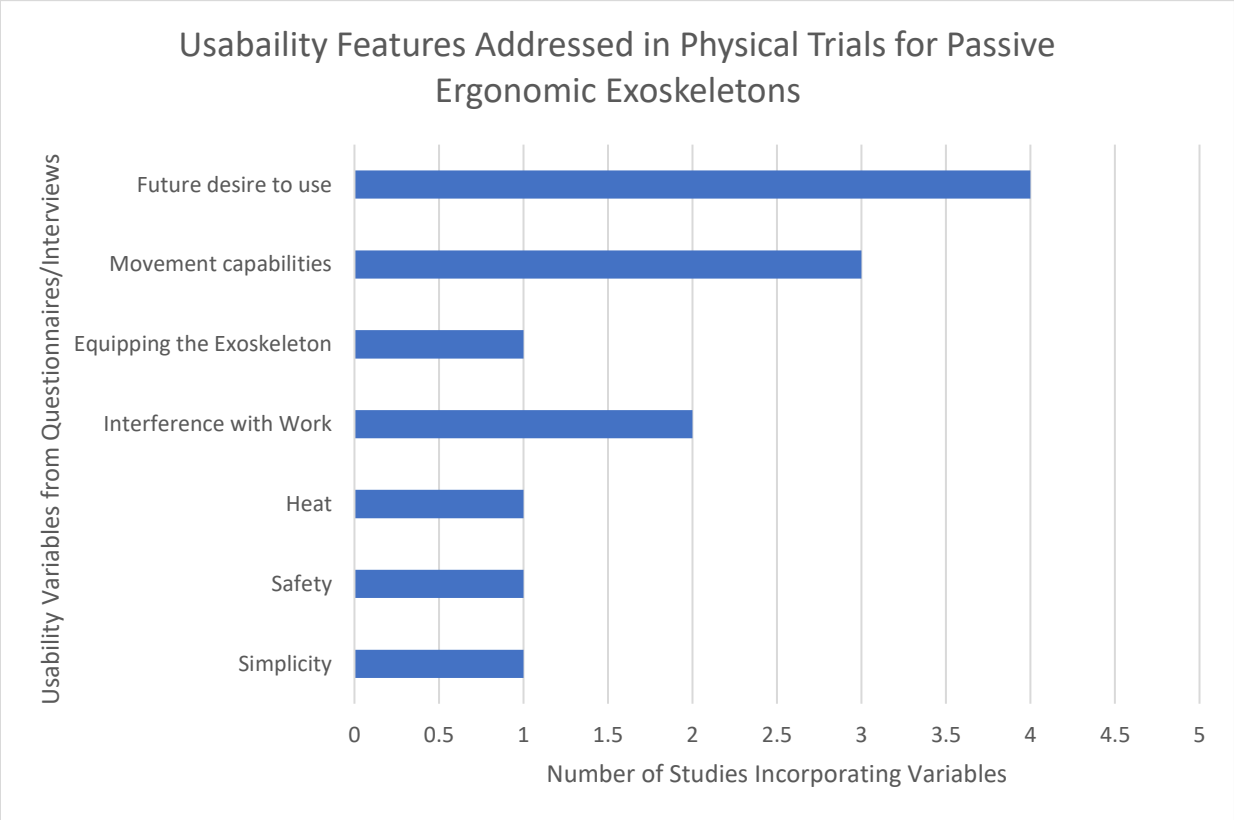

Figure 8. Usability Features Addressed in Physical Trials for Passive Ergonomic Exoskeletons

Discussion

Patterns of Exoskeleton Types and Purposes

Regardless of how each study was categorized or the outcomes that were or were not included in each article, the ultimate goal is implementation to improve the lives of surgeons and their patients. By studying the purpose of each type of exoskeleton, favorable outcomes can be identified. To progress to the next step of implementation, having as many favorable outcomes as possible would be beneficial. However, a distinct gap was revealed in the discrepancies between passive and active exoskeletons and how each category almost exclusively only has one purpose or another. Figure 4 shows that active exoskeletons are primarily associated with performance augmentations or training, which are related more to improving patient outcomes than physically helping the surgeon. Passive exoskeletons have been designed primarily for improved surgical ergonomics, although one passive exoskeleton by Nishida et al. focused on performance augmentation (2015). By having these exoskeletons only have one purpose, attempting to sell the idea of exoskeletons to surgeons may be more difficult since the inconvenience of learning and implementing an exoskeleton could easily outweigh any benefits presented, especially if the surgeon merely sees the exoskeleton purpose as ancillary.

This divergence in the purposes of passive and active exoskeletons is unremarkable but still fascinating. On the one hand, performance augmenting active exoskeletons is a natural progression of the technology as it has the potential to provide instantaneous feedback and immediately correct mistakes during surgeries, while passive exoskeletons conform to participants allowing them to be excellent support devices to improve users' ergonomics. On the other hand, despite the natural progression, the lack of variability between categories was surprising. Although active exoskeletons can provide real-time feedback to augment performances, their constant power source has the potential to be beneficial as an ergonomic

intervention by diverting some power to assist parts of the body in reducing fatigue and pain experienced by surgeons instead of being powered by other sources, such as hydraulics. Conversely, while passive exoskeletons are mainly focused on ergonomics, ergonomics and performance augmentation often go hand-in-hand; as one has better ergonomics, thereby reducing the likelihood of developing MSDs and suffering from the resulting pain, it will allow users to improve their work. Though these are merely speculations of what could happen, it is important to realize that exoskeletons do not have to be designed primarily for either performance augmentation or ergonomics; they can be made to address both simultaneously.

Along with the lack of variation in the purposes of passive and active exoskeletons, there also was a pattern in the methods in which studies were performed. Eight of the ten passive exoskeleton studies were physical trials involving participants, while four of the seven active exoskeleton studies were conceptual models. Again, this appears to be a natural evolution of the purposes of passive and active exoskeletons as improving participants' ergonomics has been defined as reducing the likelihood of developing MSDs, while augmenting performances first requires conceptual models to determine what optimal means and then the actual optimization of said process. Both methods have their advantages and disadvantages, but implementation will not be able to occur without a mix of both methods being employed.

That said, physical trials allow further investigation more so than just in conceptual models, as the study outcomes can be further analyzed, leading to the passive ergonomic exoskeletons, the subcategory involving the most human-subject testing studies, being of particular interest. The seven studies with human-subject testing provided substantial data to begin to see the patterns in outcomes that were or were not addressed.

Objective Outcomes – EMGs, IMUs, and Cognitive and Dexterity Tests

Collectively, outcomes were broken down into subjective or objective assessments. It was unsurprising to see that EMG and IMU use were utilized; however, both devices are frequently used in ergonomic studies as some of the primary metrics to evaluate physiological changes objectively, so it was somewhat surprising that of the seven passive ergonomic exoskeleton studies, only three studies used EMGs and two used IMUs. The focus on usability may explain this limited usage of EMGs and IMUs, but it was still surprising to see such a heavy emphasis on alternative subjective metrics instead of the objective results yielded by these two tools. Without an objective way of proving that these exoskeletons are usable, taking the next step of implementation becomes much more difficult as the main argument for why they should be used are primarily subjective. Considering the goal of these passive ergonomic exoskeletons was to reduce the risk of developing MSDs and decrease pain and discomfort, utilizing EMGs to show decreased muscle activations and IMUs to show improved postures like it should be one of the primary pieces of evidence as to its effectiveness.

The other objective metric observed in these studies was dexterity, as seen in two of the seven studies. Implementing dexterity testing makes sense, as a surgeon's dexterity is crucial to surgical outcomes, especially in laparoscopic surgeries. Liu et al. had the most extensive evaluations, as participants were required to perform eleven common dexterity tasks in total from the Minnesota Manuel Dexterity Test, the Purdue Pegboard Dexterity Test (PPDT), and the Fundamentals of Laparoscopic Surgery. The researchers found no significant differences in dexterity scores with or without the exoskeleton (2018). Though there was no improvement in scores, the tests could be seen as a way to ensure that surgeons' abilities were unimpaired, making the incorporation of exoskeletons into the OR a more feasible option.

The other dexterity assessment performed was in Aoki et al.'s study; instead of using a standard dexterity test, surgeons participating were asked to suture, then the number of stitches placed was recorded. It was discovered that the surgeons wearing the exoskeleton placed more sutures than when they were not wearing them in a lab setting (2020). Although this study did not use a test directly assessing dexterity, it still works to evaluate a crucial surgical skill heavily reliant on dexterity. This study found that using the exoskeleton led to an increase in the number of sutures placed relative to not wearing the exoskeleton. These results are promising, and when combined with the outcome from Liu et al.'s study testing dexterity, it appears that exoskeletons, when properly fitted and used correctly, are not detrimental to a surgeon's capabilities and may even help to augment a surgeon's abilities. Of course, these results should be cautiously accepted as there have only been two studies analyzing dexterity, with only one being in the actual OR, but the preliminary results are still promising regarding the potential benefits of exoskeletons.

Unsurprisingly, many of these studies that focused on passive ergonomic exoskeletons did not include dexterity as a primary outcome; if anything, the two studies that evaluated it included dexterity more as a constraint to ensure that the exoskeleton was not detrimental to a surgeon's performance than as a potential performance augmentation. In considering the effects of performance augmentation, though, the passive exoskeleton inadvertently began to be considered as more than just something meant for improved ergonomics; its effects could also demonstrate improved performances. Though this paper demonstrated that there currently is a distinct gap between the current states of active, performance-augmenting exoskeletons and passive, ergonomic exoskeletons, outcomes like this help demonstrate multiple potential benefits simultaneously, regardless of the original and primary purpose of each exoskeleton. By carefully considering and implementing outcomes like this into different studies, the interdependent

relationship between ergonomics and performance augmentation can be further explored, potentially adding multiple reasons why exoskeletons should at least be considered, if not implemented.

Another outcome that bridges the gap between ergonomics and performance augmentation is cognitive performance. It has been demonstrated that fatigue can negatively impact surgeons' cognitive performances (Gerdes et al., 2008; Kahol et al., 2008). Since the goal of ergonomic exoskeletons is to reduce this muscular fatigue, these exoskeletons could also be performance augmentation devices. Despite this possibility, none of the passive ergonomic exoskeletons considered the participants' cognitive performances or cognitive loads; this could be a significant missed opportunity. By synthesizing outcomes from the other types of exoskeletons to create studies analyzing multiple benefits simultaneously, there can become a much stronger argument as to why someone should consider using an exoskeleton in practice. Dexterity and cognitive performances are two of the most apparent objective metrics that may also be performance augmentations if revealed to be beneficial, but there may be additional factors that could be improved just through the use of ergonomic exoskeletons. These arguments and benefits are meaningless, though, if the technology itself is unusable.

Usability

The ultimate objective of every type of surgical exoskeleton study is the same: implementation. All implementation also requires not only a clear argument as to why or how the new technology is beneficial but also requires buy-in from the surgeons or OR staff responsible for using the equipment in the future. The researchers responsible for creating these exoskeleton studies have known this and placed a heavy emphasis on usability. In fact, six of the eight passive ergonomic exoskeleton trials asked participants about usability in some form. The actual features asked about were further investigated and shown in Figure 8. Ultimately, the most

commonly asked question was whether the wearer would want to use the device again, so basically, explicitly asking about buy-in. Though helpful in showing a general degree of buy-in, it is a much more complicated issue to say that a user wants to use a device in the future and implement it to be used every day, leading to other features being asked for related to usability.

The next most common usability question was regarding the ability to move around relative to not wearing the exoskeleton, which was very similar to the outcomes regarding dexterity. This question was asked more to ensure that no harm was being done to the wearer and less as an evaluation of a potential performance improvement. A similar question was also asked in two of the studies as it asked participants to rate whether the exoskeleton interfered with their work or environment. Asking these questions is critical as these are prototype exoskeletons, and any feedback is crucial to improving the technology to be ready to implement. However, when the purpose of asking these questions is solely on usability and nothing else, questions become worded so that the theoretical ceiling of using an exoskeleton is to do no harm and not as a potential benefit.

The remaining four categories of questions keep to this same theme of doing no harm as they ask about ease of donning/doffing the exoskeleton, heat, comfort, safety, and simplicity. Again, these questions are crucial as these features must be resolved and optimized before implementation, but by creating devices that merely do no harm, exoskeletons can seem like devices that only fix one problem and can lead to many more. Usability questions must be asked, but the goals and questions of exoskeletons must be reframed to increase buy-in. Instead of just creating ergonomic exoskeletons that decrease the risks of MSDs while never addressing any additional performance benefits, other potential performance augmentation benefits should at least be considered as a potential way to show that ergonomic exoskeletons have more benefits

than just a decrease in pain. The same can be true for the opposite case of active performance augmentation exoskeletons, as it can consider how it can incorporate potential ergonomic benefits. In both cases, demonstrating simultaneous improvements in multiple areas would be valuable in improving surgeon buy-in. Obviously, this is easier said than done, and there may not even be significant augmentations that could be done in addition to ergonomic improvements but neglecting the benefits of this union would be nonsensical.

A Multifaceted Approach for Evaluating Exoskeletons

In looking at the primary categories of exoskeletons and the patterns that arise from each type of exoskeleton and their purposes, various outcomes can be selected from each category to create a multifaceted argument as to the potential benefits of the implementation of exoskeletons. Three primary outcomes were evaluated: ergonomic interventions, performance augmentation, and, in most cases, usability. If a multifaceted approach is desired, each of these outcomes should be included. The researchers have created the following lists based on commonly performed tests or questions in the analyzed literature to provide common outcomes pertaining to each category:

Usability:

1. Would you use this exoskeleton again in the future/how likely are you to use this exoskeleton in the future?
2. How frustrating was your job relative to when not wearing the exoskeleton?
3. How well were you able to move with the exoskeleton on?
4. How did the exoskeleton interact with your work environment?
5. Was the exoskeleton itself comfortable or uncomfortable?

Ergonomics:

1. EMGs
2. IMUs
3. Biometric evaluations (i.e., heart rate, respiratory rate)
4. Reported pain levels
5. Self-reported fatigue and discomfort

Performance Augmentation:

1. Cognitive performance tests
2. Dexterity tests
3. Self-evaluation of performances
4. Did the exoskeleton make your job more or less physically demanding than without it?

Though there may be times when selecting from one or two of the categories is necessary to determine whether any changes are made initially if the strongest argument for implementation is to be made, all three of these categories should be evaluated simultaneously. Previous literature has demonstrated the compartmentalization of outcomes based on the type and purpose of each exoskeleton, but there is an inherent interdependence of features and benefits that should be considered and used to create the strongest argument as to why the implementation of this novel technology may be worth it. With that being said, there may not even be significant benefits found by incorporating other purposes, but the results would still be valuable, regardless, because at worst, an exoskeleton either would not be beneficial in any other way or would be harmful, so it could be changed to counteract these results or at best, it could be beneficial and serve as another reason for why it should be further considered.

Conclusion

Exoskeletons in the OR have demonstrated considerable potential in the areas of performance augmentation and improvements in ergonomic practices. However, studies have focused on improving one aspect exclusively and not considering potential improvements that may be inadvertently occurring. Studying all the potential benefits of exoskeletons may lead to greater buy-in among surgeons or OR staff utilizing exoskeletons in the future. The researchers listed basic questions and outcomes in each category as an initial step toward simultaneously capturing ergonomic practices, performance augmentations, and usability. Future studies incorporating all three of these categories must still be performed, and there is room for developing a standard set of outcomes and questionnaires that will include all relevant categories of exoskeleton usage.

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CHAPTER 3. SUBJECTIVE, OBJECTIVE, AND PERFORMANCE EVALUATIONS OF A HEAD AND NECK EXOSKELETON FOR SURGICAL APPLICATIONS

Joseph Kim*, Richard Stone*, Susan Hallbeck*+, Hamid Norasi*+

* Department of Industrial and Manufacturing Systems Engineering, Iowa State University

+ Robert D. and Patricia E. Kern Center for the Science of Healthcare Delivery Division of Healthcare Delivery Research Mayo Clinic Rochester, MN

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Abstract

Surgeons are susceptible to developing musculoskeletal disorders; exoskeletons have been suggested as a potential solution that may help alleviate the demands on the body. This study tested the effectiveness of a head and neck exoskeleton apparatus designed for surgeons. Eight participants were recruited who performed 12 trials each and tested out different combinations of postures (45- or 90-degrees of the neck being bent), materials (polyethylene, neoprene, or high-density foams), and activation status of the exoskeleton (activated or deactivated). Trials involved participants standing in a static posture for 20 minutes, where they would state their pain levels, perform cognitive and dexterity tests, and evaluate their experience with the exoskeleton. EMGs were also applied to the splenius cervicis, splenius capitis, and erector spinae to determine the percent muscle activations. Enabling the exoskeleton system led to decreased muscle activation, decreased changes in pain throughout each trial, and a generally favorable outlook of wanting to use the exoskeleton again. The high-density foam was shown to

[2] This chapter is currently a work in progress. It may differ in significant ways from the published version.

be the most favorable material, and it could decrease the change of overall pain during a trial. There were no significant changes in cognitive or dexterity test results.

Introduction

Surgeons are a class of workers susceptible to developing work-related musculoskeletal disorders (MSDs) due to holding awkward and risky postures for hours on end during surgical operations. There have been multiple studies reporting that a majority of surgeons in a variety of specialties will report symptoms of MSDs leading to pain in a variety of different parts of their bodies, such as the back, neck, shoulders, and arms (Catanzarite et al., 2018; Stucky et al., 2018). Despite this pain, surgeons have also reported that they do nothing to alleviate it or seek medical care as they merely see it as part of the job (Janki et al., 2017). However, this can be detrimental as surgeons who suffer from this pain have also reported that it can be experienced regularly, including while operating, which can interrupt the workflow of surgeries, even going as far as to have to stop in the middle of surgeries (Soueid et al., 2010). These potential distractions, as well as the constant distraction of pain, can adversely affect surgeons' performances, potentially leading to increased chances of harming a patient by performing a medical error (Gerdes et al., 2008; Sugden et al., 2012). Despite the selfless nature of many surgeons, this is one area worth investigating the effectiveness of different technologies or seeking out the advice of others as it can improve not only their own lives but also their patients' lives.

When compounded for thousands of cases multiple hours long performed over decades, it is no surprise that this occupation is at a higher risk of developing MSDs than other workers. For other occupations, new technologies have arisen created by human factors and ergonomics (HFE) specialists, who create devices designed for the worker and their job to increase efficiency, comfort, safety, usability, ease of use, and many other factors. Manufacturing

industries have particularly benefited from HFE specialists' through the creation of new devices and techniques that improve their work (Gillette, 2022; Gillette & Stephenson, 2018). The application of HFE to manufacturing industries is a natural application of the field as manufacturing jobs, as many are physically demanding, and efficiency can be easily studied. The optimization of workers has led to companies being incentivized to invest in HFE R&D and try out new technologies if it means that their workers can perform better or be safer.

One example that has caught on recently is the exoskeleton, which is a "wearable device that augments, enables, assists, and/or enhances physical activity through mechanical interaction with the body" (ASTM, 2021). The purposes of exoskeletons can vary from augmenting workers' performances, making them more efficient on an assembly line, to improving their safety by decreasing the risks of developing MSDs or a combination of both; in this paper, exoskeletons that are designed to improve workers' performance/effectiveness will be referred to as performance augmentation exoskeletons while exoskeletons focused on reducing the risk of MSDs for workers will be referred to as protective exoskeletons. Exoskeletons can be further classified according to their power source or lack thereof. If a continuous source of electricity is needed for the exoskeleton to function, it is known as an active exoskeleton. On the other side, exoskeletons that are powered through non-electrical means, such as hydraulics or tension forces, and do not need a continuous power source are known as passive exoskeletons.

Due to its success, the use of exoskeletons has expanded into other non-manufacturing-based fields, most notably, healthcare. A variety of healthcare specialists have been able to use exoskeletons, such as nurses (Hwang et al., 2021; Miura et al., 2021), ultrasound workers (Tetteh, Wang, et al., 2022), and in a surgical setting (Cha et al., 2019, 2020; Liu et al., 2018; Perry et al., 2007; Santoso et al., 2022; Tetteh, 2021; Tetteh, Hallbeck, et al., 2022; Tetteh,

Wang, et al., 2022; Wang et al., 2021). Considering that surgeons are particularly susceptible to developing MSDs and the success of exoskeletons in other industries, it is unsurprising to see that there have been attempts to apply exoskeletons to surgical applications.

According to a literature review performed by the researchers, there have been a few studies that have sought to assess the viability and usefulness of exoskeletons in the operating room for both performance augmentation and ergonomic exoskeletons. Performance augmentation exoskeletons designed for the OR were typically found to be active exoskeletons and focused more on the conceptual modeling of how they might improve performances, such as by creating a model that would help surgeons stabilize their hands to reduce natural tremors (Peter P. Pott et al., 2014a; Pott et al., 2014b). On the other hand, protective exoskeletons have mainly been preliminary studies that physically test exoskeletons in either a non-surgical setting, typically a university with college students, or in the OR itself as smaller-scale, pilot studies with a few champion surgeons assessing the exoskeleton. Because these are preliminary studies, most of the studies are focused on assessing and optimizing the usability and comfort of the exoskeletons to make them more viable for implementation while also determining if the exoskeletons are useful in reducing the risk of developing MSDs. These differences have led to two distinct categories: active performance augmentation exoskeletons still in their conceptual phases and passive ergonomic exoskeletons in limited pilot studies assessing the effectiveness and viability.

In assessing the two categories, there are a few gaps that arise. For active, performance augmentation exoskeletons, the gap is taking the next step from conceptual modeling of an exoskeleton to testing it with human subjects and assessing its effectiveness. Passive, ergonomic exoskeletons have already taken this step of creating exoskeletons as they are focused on

usability and beginning to pilot them, but their assessments of usability have often been limited to assessing the most basic usability characteristics, such as asking participants whether they would use the exoskeleton again or asking questions related to if the exoskeleton positively or negatively affects their work. More specific questions that may affect usability, such as simplicity, ease of equipping the exoskeleton, or a focus on the materials used, were occasionally brought up in one or two studies but not universally. Finally, there is a gap between the two categories of surgical exoskeletons, as performance augmentation and safety may have an interdependent role; the safer surgeons are by reducing the risk of them developing MSDs and therefore reducing their discomfort, the better they may perform.

This study focuses on the gaps found in passive, ergonomic exoskeletons while taking preliminary steps to bridge the gap between the two categories of surgical exoskeletons by assessing whether surgical protective exoskeletons may have performance augmenting effects, such as improved dexterity or cognitive performances. An apparatus that simulated a passive, safety-focused head and neck exoskeleton designed for surgeons was created, and participants were asked to hold two different postures (45 degrees and 90 degrees) for twenty-minute intervals. Three categories of outcomes were assessed, each corresponding to a category of surgical exoskeletons. Since this apparatus was meant to assess surgical protective exoskeletons, the first metric assessed was whether or not the exoskeleton may be effective in reducing the risk of developing MSDs; this was assessed by comparing the muscle activation of the neck and the back using electromyography (EMG) sensors of when the exoskeleton was enabled versus when it was not. This metric is not novel, but it was used as an objective assessment of whether this particular apparatus and subsequent exoskeleton designs may be useful in reducing the risk of developing MSDs, as that is the primary goal of many passive, surgical, ergonomic exoskeletons.

Additionally, the actual use of the exoskeleton was also evaluated by measuring the tension forces that participants exerted throughout each trial. Subjective metrics of pain were also analyzed before, during, and after each trial.

The next metric, however, was novel to the researchers' knowledge, as it assessed the different materials used by the exoskeleton. In previous papers, the comfort and usability of exoskeletons were evaluated, but many stuck to evaluating both features as a whole and did not break down particular aspects of either category. This study sought to break down usability and comfort even further by comparing three foams used and having participants rank their opinions of each one based on perceived comfort and thermal characteristics. This analysis looked at the overall results regardless of the participant to determine whether thermal effects or material choice impacted the usability of an exoskeleton.

The final metrics assessed sought to work in the gap between active performance augmentation surgical exoskeletons and passive safety surgical exoskeletons. This was done by assessing participants' cognitive and dexterity performances at the beginning of each trial versus at the end to determine whether using a passive safety surgical exoskeleton could yield Performance augmenting characteristics. The Purdue Pegboard Test (PPT) and Symbol Digit Modalities Test (SDMT) were administered twice during each trial to evaluate the dexterity and cognitive performances, respectively.

Prior to performing the study, the following hypotheses were formulated:

- Activation of the exoskeleton, regardless of the posture, will lead to statistically significant lower levels of muscle activation and changes in pain levels than when the exoskeleton was disabled, suggesting that exoskeletons may be a helpful technology in reducing the risk of MSDs for surgeons.

- Activation of the exoskeleton will lead to better usability scores versus when it is not activated.
- Softer materials will be more favorable than firmer headrest materials, leading to slightly statistically significant differences in surgical exoskeletons' overall perception and usability.
- Activation of the exoskeleton and levels of pain will lead to small, statistically significant differences between participants' changes in dexterity and cognitive performances. This hypothesis is based on previous literature that connected participants' cognitive attentional performances with increased fatigue (Stephenson et al., 2020).

Methods

IRB Approval

This chapter, "Chapter 3: Subjective, Objective, and Performance Evaluations of a Head and Neck Exoskeleton for Surgical Applications," received IRB Approval (see Appendix B).

Participants

Male and female participants were recruited through email from a large public university in the United States. Participants were asked to provide their age, height, and weight during an initial screening survey and whether they had any long-term/chronic head, neck, or back pain or injuries. Participants who stated that they had any form of chronic head, neck, or back pain or injuries were unable to participate in the study due to the additional fatigue that said body parts would experience. Similarly, anyone with MSDs related to the head, neck, or back was also excluded. Participants were not compensated for participation in this study.

Material Selection

Three different materials for the headrest were selected: high-density (HD) foam (31 kg/m^3), polyethylene (PE) foam (44.5 kg/m^3), and neoprene foam (77.6 kg/m^3). These materials were chosen based on their perceived comfort and range of densities. The foams were then cut to 8 inches long by 4 inches wide by 1 inch thick and then wrapped in rayon fabric.

Apparatus

An apparatus was created to replicate an exoskeleton's forces and supportive elements on participants. At their most basic, exoskeletons support users by exerting forces on specific body parts to support them; for a head and neck exoskeleton, these forces are exerted on the forehead to support the weight of the head. As a result, the apparatus used tension forces and headgear to reproduce the forces found in a head and neck exoskeleton. This device would allow the researchers to measure the forces exerted on participants by the exoskeleton without compromising the design of a pre-built exoskeleton. Additionally, because it is technically not an exoskeleton, as participants were not wearing it and it was fixed to the ground, the interaction between the apparatus and the participant could be simplified down to just how participants interacted with the headgear and not other parts of their bodies. If this were a wearable exoskeleton that was used like a backpack, then it would have interacted with other parts of the body, such as the shoulders, and there would be less of an emphasis on solely how participants interact with the critical aspect of a head and neck exoskeleton, that is, the part that exerts the force on the head.

The apparatus was created using a nylon rope that connected headgear with a headlight and adjustable rigid membrane to a metal frame behind the participant. To enable the exoskeleton, the participants put the headpiece on, positioned their heads at the appropriate angle based on the trial, and then the rope/cable was affixed to a force gauge on the metal frame and

pulled so that it was taut. Because it is taut, participants were able to rest their foreheads against the headgear to support the weight of their heads. The exoskeleton was disabled by loosening the nylon rope so there was enough slack that no tension forces were exerted during the trial.

This exoskeleton's headpiece was constructed using the inner shell of a bike helmet, a headlamp, a laser pointer, a hook, and different headrest materials for the forehead. The headlamp was made out of elastic bands on the side and a rigid plastic front. It was used to simulate the feeling of wearing a surgical headlamp and provide a rigid object to affix the laser pointer. The laser pointer was used to ensure that participants were holding the correct postures throughout the study. Because this headlamp was made of elastic bands, a rigid membrane (the inner shell of a bike helmet) was added so that participants felt constant tension forces from the nylon rope and not the elastic bands of the side of the headlamp. The rigid inner membrane was adjustable so participants could tighten or loosen it based on their comfort levels. The hook at the back was used to connect the metal frame at the back with the headgear using a nylon rope in between to exert tension forces.

The metal frame behind the participants was made out of perforated steel tubing that allowed for the height of the apparatus to be readjusted based on the participants' heights. There were two metal bars that the nylon rope was fixed to; the first contained a pulley, while the second was where a force gauge and the nylon rope were fixed. The pulley was used to replicate the construction of an exoskeleton more accurately. The head and neck exoskeleton that this device was modeled off of exerted horizontal forces to support participants' heads as they moved forward and back, but these forces were regulated in a backpack that the participants wore; the forces had to be redirected in the vertical direction to be contained and hidden in the backpack in the pre-built model. This apparatus did the same thing using a pulley as the tension forces were

exerted in a horizontal direction against participants' heads but then redirected into the vertical direction using a pulley. Once in the vertical direction, the nylon rope was fixed to the force gauge.

Participants were asked to stand with their backs facing the exoskeleton apparatus and put on the headgear. In front of the participants was a table with an SDMT and the PPT and a screen straight up in front of them. Participants adjusted the height of the table so they could comfortably perform the PPT. While standing in a comfortable position to perform the tests and wearing the headgear, the laser pointer was turned on, and a 45-degree angle of participants' heads and necks from a neutral standing posture was calculated. A target was placed so the laser would hit the target when participants were in a posture between 40 and 50 degrees. For 90 degrees, participants were asked to bend their necks as much as possible so that their chin was touching their chest. Due to the use of a laser pointer, participants were also required to wear laser safety glasses throughout the trials while the laser was enabled. The apparatus is shown in Figure 1 below. The individual headpiece is shown in Figure 2.

Figure 9. Apparatus Head Piece

Figure 10. Picture of the Testing Apparatus

General Trial Procedure

This study was a 3x2x2, random complete block design, leading to twelve trials per participant performed over two days. Participants were asked to use three headrest materials (HD foam, PE foam, and neoprene foam) at two different postures (45 degrees and 90 degrees) in the activated or deactivated states (no tension versus tension, which is also referred to as being in the experimental or control states, respectively), and participants were used as a blocking factor. Each combination of variables led was considered one trial; participants were asked to hold a particular posture for twenty minutes a trial and given ten minutes between trials to take a break. Six trials were performed each day, and participants were scheduled to be tested at least three days apart. Participants wore the headgear regardless of whether the exoskeleton was activated;

the only difference was whether the exoskeleton apparatus was “activated,” meaning the nylon rope was taut. Participants were not explicitly informed if the trial was in the activated or deactivated group. A researcher in approximately 45- and 90-degree postures can be seen in Figures 3 and 4, respectively.

Figure 11. Researcher in the 45-Degree Posture with the Apparatus Activated

Figure 12. Researcher in the 90-Degree Posture with the Apparatus Activated

At the beginning of each day, participants filled out a questionnaire asking them to rate any discomfort of particular body parts on a scale from zero to ten, with zero being no pain and ten being the worst pain imaginable. This same questionnaire would be used again at the end of

each day, at the start of each trial, and after each trial; the questionnaire can be found in the Appendix in Figure 11. The changes in pain levels for each body part between the same day and each trial were then calculated. At the end of each trial, participants were also asked to evaluate their impressions of the exoskeleton, with a particular emphasis on the forehead materials; this second page of the questionnaire can be seen in the Appendix in Figure 12.

Participants were asked to get into the appropriate posture to begin each trial. Once participants held a static posture at the appropriate position, a stopwatch and the EMG were started. Participants were asked to state their pain levels every two minutes (starting at zero minutes and ending at the twenty-minute mark). Whenever the pain levels were assessed, the tension force was also recorded. The SDMT was administered at the one-minute mark and the eighteen-minute mark, while the PPT was administered around the three-minute mark and the fifteen-minute mark. At the three, fifteen, and eighteen-minute marks, there was an overlap of the verbal pain assessment with the SDMT and PPT; whenever there was an overlap, participants were asked to verbally state their pain levels but told to continue with the test. The form used to record pain levels, force magnitudes, SDMT scores, and PPT scores can be found in the Appendix in Figure 13.

After concluding all tests on the second day, participants were asked to complete a post-study questionnaire. This questionnaire asked participants about their overall impression and perceived usability of the exoskeleton and had them rank the different materials in terms of comfort and usability. Additionally, they will be asked to identify parts of the body that were particularly fatigued during the study. This questionnaire can be found in the Appendix in Figure 14.

Questionnaires

Participants were asked to complete a total of five different types of questionnaires; pre- and post-day questionnaires, pre- and post-trial questionnaires, and an end-of-the-study survey asking them to describe their impression of the exoskeleton and materials associated with it. In both sets of pre- and post- questionnaires, a discomfort survey was administered asking participants to rate current pain levels on a scale from 0 to 10 (0 being no pain at all and 10 being the worst pain possible) of seven body parts (head (physical), head (mental), neck, upper back, lower back, left shoulder, and right shoulder). Each survey assessing pain levels was identical, allowing for the changes in pain to be calculated. On the post-trial questionnaire, a second page asked participants to evaluate the trial they had just performed. Participants were asked nine questions on this page: the degree to which the exoskeleton helped alleviate discomfort, the comfort/discomfort of the exoskeleton as a whole, the temperature of their forehead while wearing the exoskeleton, comfort/discomfort of the exoskeleton's forehead material, the ability of the forehead material to serve as a way to regulate the forehead's temperature, an evaluation of specific body part discomfort, self-perceived ability to perform cognitive tasks, whether participants would use the exoskeleton again, and an explanation on their answer to whether they would use exoskeletons or not. Each of the questionnaires can be found in the Appendix in Figure 12.

Similar to the post-trial survey, the post-study survey asked a variety of questions. Three types of preferences were asked about: their ranking of the materials and important features of the exoskeleton, their overall opinion of the exoskeleton (assessed with a seven-point Likert scale), and a short-response section asking for general opinions about features that were liked or not in the exoskeleton. This questionnaire can be seen in Figure 14 in the Appendix.

Cognitive Test – Symbol Digit Modalities Test (SDMT)

The SDMT is a test that evaluates participants' information processing speeds. Participants were provided with a set of nine symbols that correspond with a number one to nine and are displayed in a key at the top of each page. Below that key was a test that included a series of randomly ordered symbols with blank boxes under each one. Participants were asked to match as many symbols as possible to the appropriate digit according to the key for 60 seconds. The researchers then recorded the number of digits matched to the appropriate symbol. Figure 15 in the Appendix shows an example of the SDMT.

Dexterity Test – Purdue Pegboard Test (PPT)

The PPT is a dexterity test that includes four sub-tasks. A board was placed in front of the participants with four round pockets at the top and two parallel, vertical columns with 25 holes. The far left and right pockets were filled with small pins, while the two inner pockets contained washers and spacers. The first two subtasks required participants to place as many pins as possible into the vertical columns of holes using only their right and left hands for 30 seconds each. Next, participants placed pins simultaneously with their left and right hands for thirty seconds. Finally, participants had one minute to assemble using a peg, washer, spacer, and then washer) using both hands and placing them in the column corresponding to their dominant hand. At the end of each task, the researcher recorded the number of pins placed. See Figure 16 in the Appendix for a picture of the PPT.

Biometric Evaluation – Electromyography (EMG)

EMGs are non-invasive biometric monitoring devices placed on participants' skin and monitor muscles' activation levels. Three Thought Technology BioGraph Infiniti EMGs were placed on participants: one went on the left side of the lumbar erector spinae near L4-L5 (lower back), one on the left side of the splenius capitis (upper neck), and the last EMG was placed on

the left splenius cervices (lower neck). EMG sensors were placed on participants by the researchers according to SENIAM standards. Athletic tape was also used to secure the EMGs based on the researchers' discretion.

At the start of each new day, EMGs were also used to determine the maximum voluntary contraction (MVC) for the neck and the back. The MVC of the neck was discovered by having participants put their chins to their chests and then attempting to flex their heads to a neutral position while a researcher held their heads in place for three seconds. The MVC of the back was determined by having participants lay face down and halfway off an athletic table so their chest was leaning off; weight was also placed onto the participants' legs. Participants then flexed their backs toward the ceiling with as much effort as possible for three seconds while the researcher applied force down.

Statistical Analysis

Descriptive statistics were calculated with Excel. JMP Statistical Software was utilized to perform all other statistical tests. Normality was assessed for all data using a normal quantity plot or residual normal quantile plot. If normality was assumed, an Analysis of Variance (ANOVA) was performed. Participants, day number, trial number, material, exoskeleton activation, and posture were all assessed as factors. Participants were blocked for, and the differences in pain levels, dexterity test results, and cognitive test results between the beginning and end of each trial and the pain levels of body parts at the beginning and end of each day were calculated so that Student's t-tests could be performed. For analysis of trial or day number on a particular factor, bivariate fit models were created to determine if fatigue played a significant role in responses. Alpha was set at 0.05 in all cases.

Ordinal data ranking the types of materials and the importance of particular exoskeleton features were evaluated using descriptive statistics.

The rate of change of pain over time was also assessed by performing a linear fit of the rate and magnitude of change in pain over time with respect to the trial number and day to determine whether there was a significant relationship between time and changes in pain.

Python was used to analyze the EMG signals. The average of the top 10% of muscle activation signals was calculated from the MVCs, and the average of each muscle for each trial was then calculated. Artifacts were removed by removing all outliers from trial muscle data (but not in the calculation of the MVC). The percentage of muscle activation for each muscle and trial was calculated by dividing the average muscle activation for each trial and muscle by its appropriate average of the top 10% of the MVC. If participants demonstrated during their trials that the tests establishing MVCs did not reveal their true MVC, the largest average of the top 10% of that participants' trials was used as the new MVC for that muscle and day.

Results

Demographics

Initially, nine participants (seven male and two female) participants were enrolled in this study, but one was unable to complete the first day of trials due to back pain and did not return for the second day; this led to a total of eight participants (six male and two female) who successfully completed the study (age: 24.25 ± 4.56 years, height: 69.78 ± 4.62 inches, weight: 205.75 ± 70.1 pounds). Demographic information has been summarized in Table 1.

Table 5. Participant Demographics

	Range	**Average**	**Standard Deviation**
Age (years)	(19, 33)	24.25	4.56
Height (inches)	(60, 73)	69.75	4.62
Weight (pounds)	(135, 330)	205.75	70.1

Preliminary Tests

Due to participants being tested over three hours each day and the change in pain over time also used as one of the primary outcomes of participants, it was necessary to see whether fatigue over the six trials each day influenced the speed or magnitude of the change in pain over time. To determine this, the change in pain from the beginning of the trial (0 minutes) to the end of each trial (20 minutes) and the slope of pain versus time (pain level/minute) were calculated, and then both were fit to a bivariate fit model with respect to trial number. The bivariate model was done twice, once with respect to each participant and the other considering the model as a whole without breaking it up into individual participants. The graphs, r-squared, and ANOVA were observed. It was revealed that there was no correlation between the rate of change in pain over time or the magnitude of the change in pain throughout the trial with the trial number. This meant that as the study progressed and participants theoretically became more fatigued, their pain would still change in the same manner it did earlier in the study. Graphs of the change in pain over time versus the trial number and overall change in pain throughout the trial versus the trial number are shown in Figures 5 and 6, respectively. Table 2 shows the r-squared values and p-values of the ANOVA testing the entire model for both outcomes.

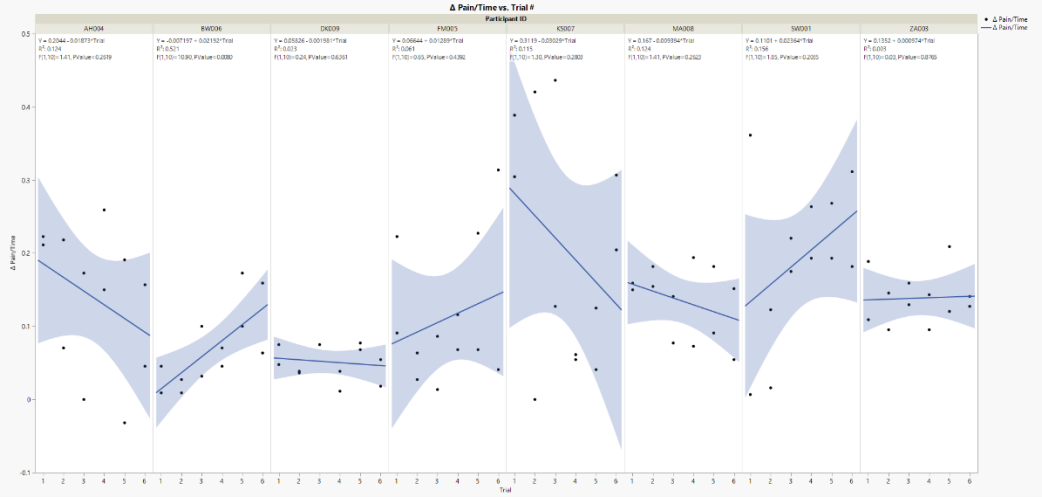

Figure 13. Change in Pain/Time versus Trial Number

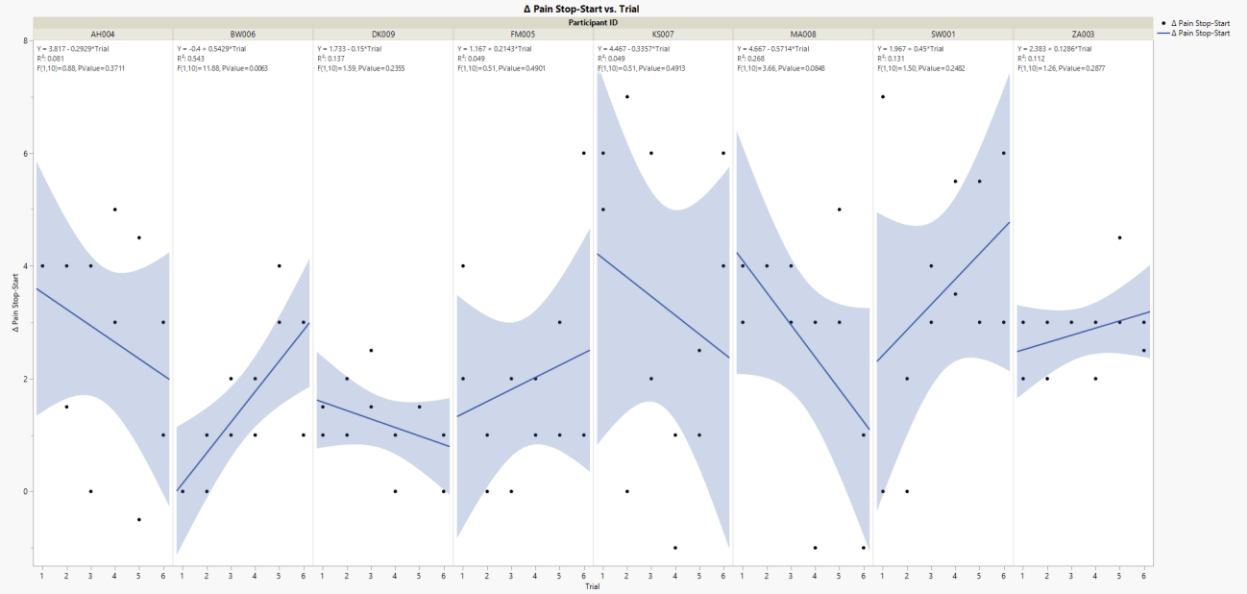

Figure 14. Overall Change in Pain versus Trial Number for Each Participant

Table 6. Statistical Analysis of Change in Pain versus Trial Number without Blocking

Source	R-Squared	Lack of Fit P-Value	ANOVA P-Value
Rate of Change in Pain/Time	$4.636 * 10^{-6}$	0.4382	0.9834
Overall Change in Pain	$2.646 * 10^{-6}$	0.4627	0.9874

Each outcome's normality was assessed using normal quantile plots and normal quantile residuals plots. If the data appeared to be normal as the data were spread evenly along the normal line, normality was assumed. All results appeared to be relatively normal, so results were able to be analyzed using traditional methods (ANOVA, Effects tests, and Student t-tests). Normal quantile plots and normal quantile residual plots can be seen in Figures 17 – 24 in the Appendix.

Overall Exoskeleton Impression

At the end of the study, participants were asked to evaluate the exoskeleton as a whole and provide their impressions of how the use of the exoskeleton went. A 7-Point Likert scale was used to evaluate seven characteristics, with one being "Strongly Disagree" and seven being

"Strongly Agree." The seven questions that were asked can be seen in Figure 14 and are further described in the methodology section. Table 3 displays descriptive statistics of participants' overall impressions of using the exoskeleton.

Table 7. Descriptive Statistics of Overall Exoskeleton Impression

Source	Mean	Standard Deviation	Minimum	Maximum
Use of exo. in the future	5.625	1.995530721	1	7
Exo. reducing demand	6	1.414213562	3	7
Frustration with the exo.	3.875	1.642080562	2	7
Movement with the exo.	4.5	1.690308509	2	7
Interacting with environment	3.25	1.832250763	2	7
Impact on PPT	4.25	2.052872552	1	7
Impact on SDMT	4.125	2.167124494	1	7

Along with the evaluation of the exoskeleton in the final survey, participants were also asked to evaluate the exoskeleton after each trial and address various properties such as comfort, temperature, and the material used. The complete questionnaire can be found in Figure 12. One of the most straightforward questions, though, asked participants to give a yes or no answer to whether they would use the exoskeleton in the future based on the trial they had just performed. The proportions of yes and no responses were analyzed using a Chi-Square test of the entire model to determine significance; Table 4 shows these results and demonstrates strong evidence to conclude that there were significant differences between yes and no responses based on the factors involved.

Table 8. Chi-Square Test Results of Exoskeleton Usage Again

Source	ChiSquare	Prob>ChiSq
Exoskeleton use again	112.8681	<.0001*

The significance of the Chi-Square test allowed an effects test to be analyzed; its Chi-Square scores and its respective P-Values are in Table 5, with statistically significant results in red text. The effects test revealed that the participant, trial number, and the activation properties each influenced responses regarding whether the exoskeleton was desired to be used again.

Table 9. Effect Test of Exoskeleton Usage Again

Source	**L-R ChiSquare**	**Prob>ChiSq**
Participant ID	71.6163784	<.0001*
Day #	2.44306323	0.1180
Trial	4.21986091	0.0400*
Material	3.41027e-6	1.0000
Activation	73.6112693	<.0001*
Material*Activation	2.42453e-6	1.0000
Posture	5.16791e-8	0.9998
Material*Posture	1.8995e-5	1.0000
Activation*Posture	4.50051e-6	0.9983
Material*Activation*Posture	1.49245e-6	1.0000

Because participants were considered a blocking factor and participants' results were independent of one another, further analysis was unnecessary, knowing that individual participants had a significant effect on their responses. The other significant factor that was brought up that was not one of the three independent variables controlled for was the trial number. A logistic fit was plotted to the relationship between participants' responses regarding

using the exoskeleton and trial number. Results of the Chi-Squared test (Chi-Square = 0.177015, P-Value = 0.6740) revealed that the trial number was not statistically significant when explaining participants' responses by itself.

The other effect revealed to be statistically significant was whether the exoskeleton was activated. The effects of the activation state on their responses were analyzed using joint and marginal probabilities (Tables 6 and 7), Likelihood Ratio and Pearson tests (Table 8), and the mosaic plot (Figure 7). All the tests revealed that the activation state of the exoskeleton was a significant factor in explaining participants' responses to these questions due to both having P-Values of less than 0.0001. Additionally, when looking at the mosaic plot and the joint probabilities, a clear pattern arises where participants in the control group (deactivated group) were much more likely to say that they would not use the exoskeleton, while participants in the activated group (experimental) were more likely to want to use the exoskeleton again in the future.

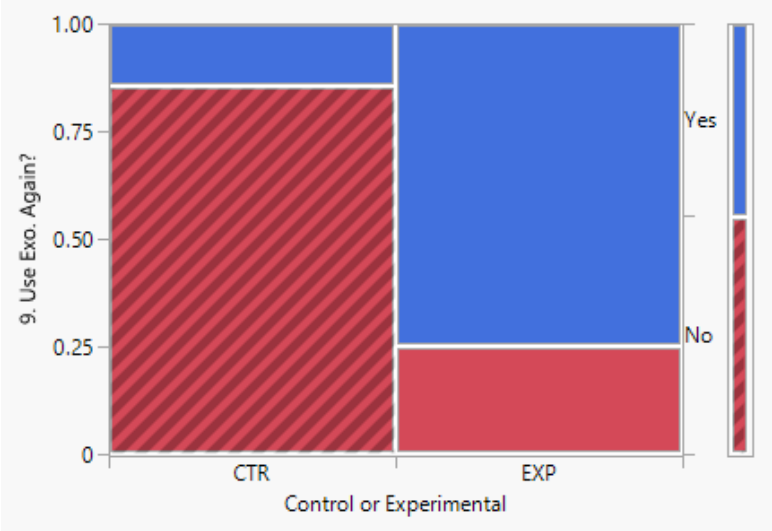

Figure 15. Mosaic Plot of Exoskeleton Usage Again by Control versus Experimental

Table 10. Joint Probabilities of Exoskeleton Usage Again by Control versus Experimental

	Exoskeleton Usage Again			
Activation	*n* *(% Total)*	*Yes*	*No*	*Total*
	Control	7 (7.29%)	41 (42.71%)	48 (50.00%)
	Experimental	36 (37.50%)	12 (12.50%)	48 (50.00%)
	Total	43 (44.79%)	53 (55.21%)	96 (100.00%)

Table 11. Marginal Probabilities of Exoskeleton Usage Again by Control versus Experimental

	Exoskeleton Usage Again			
Activation	n (% Total)	Yes	No	Total
	Control	7 (14.58%)	41 (85.42%)	48 (50.00%)
	Experimental	36 (75.00%)	12 (25.00%)	48 (50.00%)
				96 (100.00%)

Table 12. Likelihood Ratio and Pearson Test Results of Exoskeleton Usage Again by Control versus Experimental

Test	ChiSquare	Prob>ChiSq
Likelihood Ratio	38.177	<.0001*
Pearson	35.426	<.0001*

Participants were not only asked to answer yes or no to whether or not they would use the exoskeleton but also about additional properties that may have influenced their responses, such as the alleviation of discomfort and material properties. An ANOVA was performed to see if any factors would affect the responses to these questions; results can be seen in Table 9 below, which states the F Ratio and the P-Value. Statistically significant differences were revealed in all but one of the questions, which was the one focused on material discomfort.

Table 13. ANOVA Results for General Exoskeleton Impressions After Each Trial

Source	F Ratio	Prob > F
Exoskeleton alleviation of discomfort (0 = no help, 10 = helpful)	8.1901	<.0001
Exoskeleton discomfort (0 = uncomfortable, 10 = comfortable)	2.0950	0.0116
Forehead temperature (0 = normal temperature, 10 = burning)	5.0733	<.0001
Forehead discomfort (0 = uncomfortable, 10 = comfortable)	1.6757	0.572
Material temperature regulation (0 = cold, 10 = hot)	14.8740	<.0001
Cognitive performance (0 = impaired, 10 = normal)	9.4074	<.0001

Further analysis of these questions was performed by using an effects test on all questions with significant ANOVA results. Table 10 shows the effects test results for each question in the columns and potential factors in the rows. The F Ratios are shown as the first number, while the

p-values are shown in parentheses on the line below the F Ratio; statistically significant results (p-values < 0.05) are shown in red text. Results of the effects test revealed that individual participants were influential in all but one of the questions: the exoskeleton's overall effects on comfort. Due to the participant being regarded as a blocking factor, further analysis could be ignored.

Table 14. Summarized Effect Tests' F Ratios (Prob > F) for Exoskeleton Impressions

Source	Exoskeleton Alleviation of Discomfort	Exoskeleton Comfort	Forehead Temperature	Material temperature regulation	Cognitive Performance
Participant ID	3.4766 (0.0028)	1.0895 (0.3786)	12.7266 (<.0001)	40.6739 (<.0001)	24.9541 (<.0001)
Day #	11.5352 (0.0011)	0.9808 (0.3252)	1.4274 (0.236)	1.001 (0.3203)	0.1404 (0.7089)
Trial	0.6766 (0.4134)	0.0822 (0.7751)	0.2228 (0.6383)	0.925 (0.3392)	0.1121 (0.7387)
Material	0.1802 (0.8355)	0.3059 (0.7374)	2.9647 (0.0577)	1.2596 (0.2897)	0.5675 (0.5694)
Activation	129.5248 (<.0001)	26.8867 (<.0001)	0.1843 (0.6689)	1.5904 (0.2112)	5.1091 (0.0267)
Material* Activation	0.1821 (0.8339)	0.244 (0.7841)	0.2721 (0.7625)	0.0549 (0.9466)	0.3337 (0.7173)
Posture	3.8277 (0.0541)	0.3757 (0.5418)	0.0599 (0.8074)	0.1205 (0.7294)	0.5238 (0.4715)
Material* Posture	2.0278 (0.1388)	0.5595 (0.5738)	1.7689 (0.1776)	0.5041 (0.6061)	0.031 (0.9695)
Activation * Posture	0.0074 (0.9319)	3.2146 (0.077)	0.1389 (0.7104)	3.2819 (0.0741)	3.7821 (0.0556)
Material* Activation *Posture	0.9841 (0.3785)	0.3798 (0.6853)	0.2849 (0.7529)	1.3513 (0.2651)	0.3668 (0.6942)

The other relevant factors analyzed were the day number and the interaction between the activation and posture. The day number was analyzed by applying fit to the day number versus the reported exoskeleton discomfort alleviation. The chi-square test (F Ratio = 0.8393, P-Value =

0.3619) results were not statistically significant, indicating that there was not a significant enough difference in responses based on the test being performed on day one or day two. For the interaction between activation and posture and its effects on comfort, a student's T-Test was performed; these results can be found in Table 11 below, which show the least square means, and levels that are significantly different have different letters from one another. The results revealed significant differences when the activated (control) or deactivated (experimental) versions were used, with participants reporting much lower scores whenever the deactivated version was used instead of the activated version. On average, the activated version with the 45-degree posture caused the highest scores, while the deactivated version with the 90-degree posture resulted in the lowest scores.

Table 15. Least Squares Means and Student's t-test of Comfort Evaluation Comparing the Interaction Between Control and Experimental with Posture Alleviation

Level			**Least Sq Mean**
EXP,45	A		7.2938652
EXP,90	A		6.3161639
CTR,45		B	1.9774420
CTR,90		B	1.0791957

Levels not connected by the same letter are significantly different.

Although the interaction between the activation and postures was being studied, it was more evidence of significant differences between the activation statuses. This factor was the final significant effect on participants' responses; it appeared to influence the alleviation of discomfort, the general comfort of the exoskeleton, and self-reported cognitive performance

metrics. Each of these responses used Student's t-tests, and their least squared means and means were also observed. The results of this analysis can be seen in Table 12, which has the responses in each column and the activation level in the rows. The least-square means are reported in each cell, and the means are shown on the second line in parentheses. Significant differences (p-value < 0.05) were shown using an asterisk sign in the column heading for each response. These results revealed that the activation status did have a statistically significant effect on these three responses. In all three of these cases, the activated version of the exoskeleton led to more favorable responses than the deactivated exoskeleton.

Table 16. Least Squares Means (Means) and Student's t-test Results Comparing Deactivated and Activated Exoskeleton Alleviation of Discomfort, Exoskeleton Discomfort, and Lower Back

Source	**Exoskeleton Alleviation of Discomfort***	**Exoskeleton Comfort***	**Cognitive Performance***
Deactivated	1.5283 (1.6458)	2.9845 (3.0208)	7.6122 (7.6042)
Activated	6.8050 (6.6875)	5.5155 (5.4792)	8.2003 (8.2083)

* indicates significant differences between levels with Student's t-test

Overall Results

In each post-trial survey, participants were asked to evaluate the exoskeleton and its features as a whole; however, they were also asked to report their pain levels of individual body parts before and after each trial. This metric, along with EMGs to show the percentage of muscle activation and cognitive and dexterity tests, provided a more objective look at each combination

of factors in the trials. An ANOVA was performed to analyze individual body parts' percent muscle activations, changes in pain of specific body parts, and changes in cognitive and dexterity test scores. Table 13 reports each factor's F Ratios and p-values; statistically significant results are shown in red text. Each of the three muscles analyzed revealed statistically significant differences, and changes in pain were significant in all but three body parts (head physically, head mentally, and in the right shoulder), but there were no significant differences in changes in cognitive and dexterity test scores. In subsequent sections, significant effects will be further broken down for each factor.

Table 17. Summarized ANOVA Results for Objective Metrics

Source	**F Ratio**	**Prob > F**
Percent Muscle Activation		
Splenius Cervices % Activation	8.0741	<.0001
Splenius Capitis % Activation	7.4018	<.0001
Erector Spinae % Activation	27.2406	<.0001
Change in Pain – Trial		
Δ Head (physical) Pain	1.4731	0.1171
Δ Head (mental) Pain	1.2263	0.2580
Δ Neck Pain	2.5629	0.0018
Δ Upper Back Pain	2.9351	0.0004
Δ Lower Back Pain	3.8907	<.0001
Δ Left Shoulder Pain	2.1135	0.0107
Δ Right Shoulder Pain	1.4418	0.1302
Δ Pain/Time	3.2719	0.0001
Δ Overall Pain	3.0000	0.0003
Cognitive and Dexterity Tasks		
Δ SDMT Scores	0.8413	0.6891
Δ PPT Right Hand Scores	0.6806	0.8327
Δ PPT Left Hand Scores	0.8445	0.6536
Δ PPT Both Hands Scores	0.7248	0.7886
Δ PPT Assembly Scores	0.8433	0.6550

Muscle Activation

The ANOVA performed on each of the studied muscles revealed strong, statistically significant evidence (each of the p-values was less than 0.0001) to conclude that there were differences between muscle activation percentages. These results have been summarized in table 14 below.

Table 18. ANOVA Results for Percent Muscle Activation

Source	F Ratio	Prob > F
Splenius Cervices % Activation	8.0741	<.0001
Splenius Capitis % Activation	7.4018	<.0001
Erector Spinae % Activation	27.2406	<.0001

Because there was statistical significance between the percent muscle activations of each muscle as indicated by the ANOVA, effects tests were performed on each muscle. Results of this analysis are shown in Table 15, with studied muscles in the columns and factors and their interactions in the rows. Each cell includes the F Ratio and p-value in parentheses in the cells. Statistically significant results (p-value < .0001) are shown in red text. These results revealed that the participant and the activation status caused differences in muscle activation percentages for all three muscles. The participant was included as a blocking factor, so no further analysis was performed. Additionally, the day influenced the activation percentage of the splenius cervices, and the posture affected the activation of the erector spinae.

Table 19. Summarized Effects Test Results for Percent Muscle Activations

Source	Splenius Cervices	Splenius Capitis	Erector Spinae
Participant ID	23.5714 (<.0001)	19.0067 (<.0001)	78.0332 (<.0001)
Day #	4.1418 (0.0457)	0.3899 (0.5344)	0.2196 (0.6408)
Trial	1.0658 (0.3055)	3.8096 (0.0551)	0.1495 (0.7002)
Material	0.8725 (0.4225)	1.2096 (0.3047)	0.9519 (0.391)
Activation	9.4211 (0.0031)	18.7421 (<.0001)	11.1967 (0.0013)
Material*Activation	0.1082 (0.8976)	0.4677 (0.6285)	1.1875 (0.3112)
Posture	0.2021 (0.6545)	0.25 (0.6187)	5.6832 (0.0199)
Material*Posture	0.1835 (0.8327)	0.5264 (0.5931)	0.1929 (0.825)
Activation*Posture	1.7763 (0.187)	0.5316 (0.4684)	1.6159 (0.2079)
Material*Activation*Posture	0.8172 (0.4459)	0.7907 (0.4577)	0.3366 (0.7153)

The effects of the activation status of the exoskeleton on the muscles were analyzed by observing the least squares means and means and performing Student's t-tests; these results can be seen in Table 16 below, with least square means being shown in each of the cells followed by the mean in parentheses on the next line. Statistically significant differences (p-value < 0.05) were indicated using an asterisks symbol. These results revealed that the activated exoskeleton resulted in statistically significant lower degrees of muscle activation in all three muscles than when the exoskeleton was deactivated.

Table 20. Least Squares Means (Means) and Student's t-test Results Comparing Activations of Percent Muscle Activation of Individual Muscles

Source	Splenius Cervices*	Splenius Capitis*	Erector Spinae*
Deactivated	52.53% (52.89%)	33.19% (32.48%)	19.80% (19.93%)
Activated	41.39% (40.08%)	23.43% (22.65%)	15.55% (15.68%)

* indicates significant differences between levels with Student's t-test

Effects of the postures on the muscle activation percentages of the erector spinae were analyzed by observing the least squares means and means and performing Student's t-tests; these results can be seen in Table 17 below, with least square means being shown in each of the cells followed by the mean in parentheses on the next line. Statistically significant differences (p-value < 0.05) were indicated using an asterisks symbol. These results revealed that when the 90-degree posture was held, it led to greater muscle activation percentages in the erector spinae than in the 45-degree posture.

Table 21. Least Squares Means (Means) and Student's t-test Results Comparing Muscle Activation Percentages of Erector Spinae Between 45 and 90-Degree Postures

Source	Erector Spinae Muscle Activation Percentages*
45	15.95% (15.81%)
90	19.53% (19.36%)

* indicates significant differences between levels with Student's t-test

The final factor that appeared to influence the percent muscle activations was the day number and its effects on the muscle activation of the left splenius cervicis. A bivariate, linear fit testing the effects of the day number's effect on the percent muscle activation was performed; this test indicated that there was not a strong, statistically significant relationship (F Ratio = 3.4369, p-value = 0.0671) between the day number and the percent muscle activation. However, it was nearly statistically significant, so the relationship between the two variables was still observed using a scatterplot with the linear fit, as shown in Figure 8. This revealed that there might be a positive, linear relationship between the muscle activation percentage with the day number, potentially suggesting that fatigue may have been a factor. However, this should only be considered as statistical significance was not established.

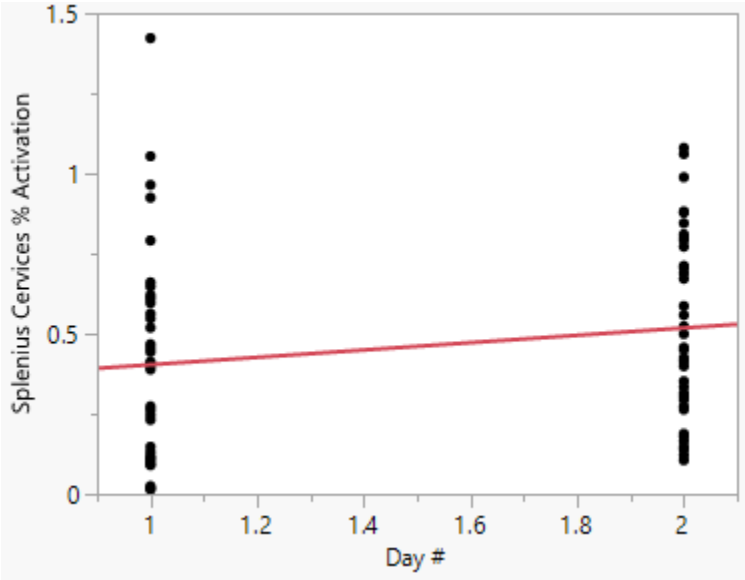

Figure 16. Bivariate Linear Fit Model Between Splenius Cervices Percent Muscle Activation with Day Number

Change in Pain – Trial

The ANOVA results analyzing the changes in pain of individual body parts indicated that there was strong, statistically significant evidence that there were differences in the changes in

pain of the neck, upper back, lower back, left shoulder, rate of change in pain over time, and the overall change in pain throughout a trial. All p-values other than the change in left shoulder pain were less than 0.0020, and the change in left shoulder pain had a p-value of 0.0107.

Table 22. ANOVA Results for Changes in Pain Throughout a Trial

Source	**F Ratio**	**Prob > F**
Δ Head (physical) Pain	1.4731	0.1171
Δ Head (mental) Pain	1.2263	0.2580
Δ Neck Pain	2.5629	0.0018
Δ Upper Back Pain	2.9351	0.0004
Δ Lower Back Pain	3.8907	<.0001
Δ Left Shoulder Pain	2.1135	0.0107
Δ Right Shoulder Pain	1.4418	0.1302
Δ Pain/Time	3.2719	0.0001
Δ Overall Pain	3.0000	0.0003

Due to the statistical significance of the changes in pain, effects tests were performed using each factor and appropriate interactions. Results of this analysis are shown in Table 19, with changes in pain of individual body parts in the columns and factors and their interactions in the rows. Each cell includes the F Ratio and p-value in parentheses in the cells. Statistically significant results (p-value < .0001) are shown in red text. These results revealed that individual participants' characteristics affected the magnitudes of the changes in pain in the upper back, lower back, left shoulder, the rate of the change in pain over time, and the overall change in pain throughout the trial. These results were not further analyzed as they were considered a blocking factor. Activation of the exoskeleton was the most influential factor in each of the changes in pain, as it affected all the statistically significant changes in pain. The next most influential factor was the participants' posture, which significantly affected the changes in neck pain, the rate of

change in pain over time, and the overall change in pain over time. Additionally, the day number affected the change in neck pain, the trial number affected the change in upper back pain, and the material affected the overall change in pain from the beginning to the end. Of the significant interaction effects, the interaction between the material and the posture affected the change in left shoulder pain, and the interaction between the material, activation, and posture affected the change in upper back pain. Each of these results will be subsequently broken down in the following sections.

Table 23. Effects Test Results for Significant Results of Individual Body Part Pain During Trials

Source	Δ Neck Pain	Δ Upper Back Pain	Δ Lower Back Pain	Δ Left Shoulder Pain	Δ Pain/Time	Δ Overall Pain
Participant ID	1.5791 (0.1547)	3.4853 (0.0027)	7.7175 (<.0001)	2.292 (0.0359)	5.2763 (<.0001)	3.3861 (0.0034)
Day #	6.3456 (0.0139)	0.6686 (0.4161)	3.7546 (0.0564)	0.6716 (0.4151)	3.4391 (0.0676)	2.1993 (0.1423)
Trial	3.2785 (0.0742)	6.709 (0.0115)	0.9097 (0.3433)	2.2493 (0.1379)	0.0687 (0.794)	0.0055 (0.9408)
Material	1.7242 (0.1853)	0.8249 (0.4422)	1.6647 (0.1962)	0.3653 (0.6952)	1.0279 (0.3627)	3.143 (0.0489)
Activation	16.4232 (0.0001)	7.0729 (0.0096)	6.2243 (0.0148)	2.9667 (0.0891)	11.2099 (0.0013)	12.9494 (0.0006)
Material*Activation	0.5722 (0.5668)	0.8132 (0.4473)	2.9302 (0.0595)	1.0121 (0.3683)	1.3859 (0.2564)	1.5825 (0.2122)
Posture	7.3424 (0.0083)	1.4014 (0.2402)	3.1244 (0.0812)	2.8661 (0.0946)	5.3911 (0.023)	10.208 (0.002)
Material*Posture	0.6672 (0.5161)	1.1818 (0.3124)	0.0202 (0.98)	4.2923 (0.0172)	0.2886 (0.7501)	0.2297 (0.7953)
Activation*Posture	0.8687 (0.3543)	0.9977 (0.3211)	0.4301 (0.5139)	0.589 (0.4452)	0.5863 (0.4463)	0.43 (0.514)
Material*Activation*Posture	0.7529 (0.4745)	4.9824 (0.0093)	0.1717 (0.8426)	2.3511 (0.1022)	2.0803 (0.132)	1.3544 (0.2644)

Least squares mean, means, and Student's t-tests were analyzed to see the differences in

the changes in pain for when the exoskeleton was deactivated versus when it was activated; these results can be seen in Table 20 below, with least square means being shown in each of the cells followed by the mean in parentheses on the next line. Statistically significant differences (p-value < 0.05) were indicated using an asterisks symbol. Significant differences were revealed in each of the changes in pain. Similar to the trend found in percentages of muscle activation, each of the changes in pain was higher in the deactivated version of the exoskeleton and lower in the activated version of the exoskeleton. Additionally, the change in pain rate was greater in the deactivated exoskeleton than in the activated exoskeleton, indicating that participants had higher levels of pain faster when the exoskeleton was deactivated.

Table 24. Least Squares Means (Means) and Student's t-test Results Comparing Deactivated and Activated with Changes in Individual Body Parts Pain

Source	Δ Neck Pain*	Δ Upper Back Pain*	Δ Lower Back Pain*	Δ Left Shoulder Pain*	Δ Pain/ Time*	Δ Overall Pain*
Deactivated	2.5102 (2.4583)	1.7152 (1.7083)	1.1753 (1.1458)	0.6729 (0.6875)	0.1582 (0.1560)	3.0558 (3.0208)
Activated	1.1773 (1.2292)	1.0140 (1.0208)	0.5956 (0.6250)	0.3480 (0.3333)	0.1024 (0.1047)	1.8817 (1.9167)

* indicates significant differences between levels with Student's t-test

The same analysis (least squares means, means, and Student's t-tests) was also done on the differences between postures and their effects on the change in neck pain, rate of change in pain over time, and changes in overall pain; these results are reported in Table 21 below. Again, in a similar pattern to the percentage of muscle activations, the 90-degree posture led to higher magnitudes in changes of pain over time than the 45-degree posture.

Table 25. Least Squares Means (Means) and Student's t-test Results Comparing Changes in Pain Between 45 and 90-Degree Postures

Source	Δ Neck Pain	Δ Pain/Time	Δ Overall Pain
45	1.3830 (1.4792)	0.1103 (0.1149)	1.9298 (2.0000)
90	2.3045 (2.2083)	0.1503 (0.1457)	3.0077 (2.9375)

A novel factor that did not appear to have an impact on the percentage of muscle activation but did appear to influence the change in overall change in pain was the type of material used. A Student's t-test was conducted, and the results and least square means are reported in Table 22 below. These results indicated a significant difference p-value < 0.05) between the HD foam and the other two types of materials. It appeared that HD foam led to a smaller change in overall pain relative to the other two materials, and the other two materials had about equal magnitudes in changes in the overall pain relative to one another.

Table 26. Least Squares Means and Student's t-test Results Comparing Changes in Pain Between Material Types

Level			**Least Sq Mean**
Neoprene	A		2.7697877
PE	A		2.7437772
HD		B	1.8926851

Levels not connected by the same letter are significantly different.

The other two factors that appeared to influence changes in pain were the day number versus the changes in neck pain and the trial number versus changes in upper back pain. Bivariate, linear fit testing was performed for both of these relationships. For the change in neck pain versus day number, there was not a strong, statistically significant relationship (F Ratio = 3.4474, p-value = 0.0665). Just like how the percent muscle activation of the splenius cervicis versus the day was almost statistically significant, this relationship was also almost statistically significant. The relationship between the two variables can be seen in Figure 9, which shows a scatterplot with the linear fit between the day number and changes in neck pain. Opposite of the muscle activation of the splenius cervicis, there might be a negative, linear relationship between the muscle activation percentage with the day number. However, these results are not statistically significant and are included only as a consideration.

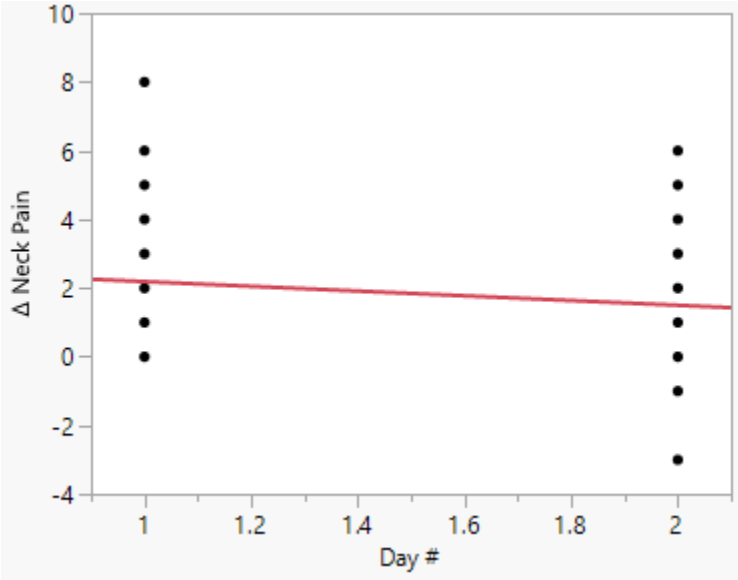

Figure 17. Bivariate Linear Fit Model Between Changes in Neck Pain and Day Number

When the bivariate fit testing was conducted on the relationship between the change in upper back pain versus the trial number, there was a strong, statistically significant relationship (F Ratio = 6.2021, p-value = 0.0145). Parameter estimates were then performed, revealing that

the trial number somewhat appeared to influence the changes in upper back pain over time (t-ratio = 2.49, p-value = 0.0145). Figure 10 shows the linear fit on a scatterplot of the changes in upper back pain over time relative to the trial number; there appears to be a positive, linear relationship between the variables, indicating that as the trials continue, there is an increase in the change of upper back pain. However, looking at the scatterplot itself and the R-squared value (0.061895), a linear relationship is probably inappropriate for this model as there is a massive amount of variance, and the linear relationship does little to explain it all, and there does not appear to be a logical relationship between the variables. With that being said, using the linear fit model still suggests that as the trial progress, there are also greater changes in upper back pain.

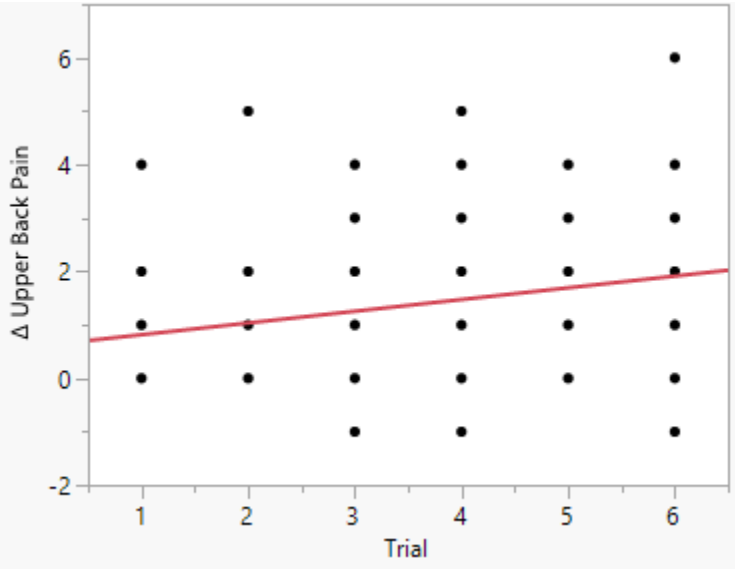

Figure 18. Bivariate Linear Fit Model Between Changes in Neck Pain and Day Number

Along with the individual factors and their effects on the changes in pain, a couple of interactions revealed statistically significant differences. The first was the interaction between material and posture and its effect on the change in left shoulder pain. Least squares means and Student's t-tests have been shown in Table 23 below; these results revealed that the combination

of PE foam and a 90-degree posture led to the greatest increases in left shoulder pain, while the use of neoprene foam with either posture and PE foam with a 45-degree posture led to the lowest changes in left shoulder pain.

Table 27. Least Squares Means and Student's t-test Results Comparing Changes in Pain in Left Shoulder Pain Between the Interaction Between Material Types and Posture

Level			**Least Sq Mean**
PE,90	A		1.1688626
HD,45	A	B	0.5637111
HD,90	A	B	0.5133059
Neoprene,45		B	0.4561827
Neoprene,90		B	0.3444433
PE,45		B	0.0159943

The final interaction studied was between the material type, exoskeleton activation, and posture. A Student's t-test was conducted, and results with the least square means were displayed in Table 24 below. These results revealed that the PE and neoprene foams, deactivated exoskeleton when holding the 90-degree posture led to the most significant changes in upper back pain, while the HD foam with the activated exoskeleton while holding the 45-degree posture led to the smallest changes in pain. In general, similar trends were seen in the exoskeleton activation and postures held, as exoskeleton activation and the 45-degree posture generally led to lower changes in pain than when it was deactivated or participants had to hold a 90-degree posture.

Table 28. Least Squares Means and Student's t-test Results Comparing Changes in Pain of the Upper Back Studying the Interaction Between Material Types, Exoskeleton Activation, and Posture

Level				Least Sq Mean
PE, CTR, 90	A			2.5412215
Neoprene, CTR, 90	A			2.4947723
HD, CTR, 45	A	B		2.0595755
Neoprene, EXP, 45	A	B	C	1.7176984
PE, CTR, 45	A	B	C	1.4109938
Neoprene, EXP, 90		B	C	1.0617323
PE, EXP, 90		B	C	1.0426570
HD, EXP, 90		B	C	1.0271739
HD, CTR, 90		B	C	0.9882092
Neoprene, CTR, 45		B	C	0.7963492
PE, EXP, 45		B	C	0.7912215
HD, EXP, 45			C	0.4433954

Levels not connected by the same letter are significantly different.

Cognitive and Dexterity Tests

The final objective metrics that were analyzed were the changes in results of the cognitive and dexterity tests from the start of each trial to the end. ANOVAs were done on each test, and their results are reported in Table 25. None of the differences in test results were statistically significant, as each had p-values greater than .6500. This lack of significance meant that no further tests could be performed.

Table 29. ANOVA Results for Changes in Cognitive and Dexterity Tasks

Source	F Ratio	Prob > F
Δ SDMT Scores	0.8413	0.6891
Δ PPT Right Hand Scores	0.6806	0.8327
Δ PPT Left Hand Scores	0.8445	0.6536
Δ PPT Both Hands Scores	0.7248	0.7886
Δ PPT Assembly Scores	0.8433	0.6550

Material Evaluation

Along with evaluating the exoskeleton itself, participants were also asked to rank the three different types of materials they used and the importance of the features of the exoskeleton, with one being the most essential/favorable and the highest number being the least essential/favorable. Descriptive statistics (mean, standard deviation, minimum, and maximum) of the rankings can be seen in Table 26 below. In comparing the materials' rankings, HD foam had the lowest average for all three categories (overall, comfort, and temperature control), indicating that it was the most favorable. Neoprene foam was the second most favorable for both the overall and comfort rankings, but the PE and neoprene foams tied for second in terms of temperature control. PE foam was seen as the least favorable in all three rankings. The ranges of these rankings should also be noticed as they can also provide insight into particularly favorable or unfavorable results. For the overall and comfort rankings, the PE foam has a minimum of two in both cases, suggesting that it was never considered the best or most comfortable of the eight participants. Conversely, HD foam had a maximum ranking of two in the comfort ranking, meaning it was never considered the least comfortable material.

For the exoskeleton property ratings, the force applied by the exoskeleton on the participant was the most important feature, followed by a tie of the importance of the softness of the material and the frustration that the exoskeleton caused. Finally, the temperature regulation of the material was rated as the least important feature. Participants never rated the force as the least important feature, while temperature regulation was never considered the most crucial feature.

Table 30. Descriptive Statistics of Material Rankings

Source	Mean	Std Dev	Minimum	Maximum
Overall Ranking				
High-Density Foam	1.5	0.7559	1	3
Neoprene Foam	1.875	0.8345	1	3
Polyethylene Foam (PE)	2.625	0.5175	2	3
Comfort Ranking				
High-Density Foam	1.125	0.3536	1	2
Neoprene Foam	2.125	0.6409	1	3
Polyethylene Foam (PE)	2.75	0.4629	2	3
Temperature Control Ranking				
High-Density Foam	1.75	0.8864	1	3
Neoprene Foam	2.125	0.8345	1	3
Polyethylene Foam (PE)	2.125	0.8345	1	3
Exoskeleton Properties Ranking				
Temperature	3.125	0.8345	2	4
Softness	2.625	1.1877	1	4
Force	1.625	0.9161	1	3
Frustration	2.625	1.1877	1	4

Discussion

Non-Exoskeleton Findings

In this study, three independent variables were controlled for (exoskeleton activation, posture, and materials), and three other independent variables were naturally incorporated into the experiment (participant, day, and trial number), leading to a total of six variables being studied. Of those six, the main factors that were attempted to be studied were the exoskeleton activation, materials, and postures. Participants were a natural block that was going to be incorporated as the study dealt with self-perceived pain scales, usability, and results of cognitive and dexterity tests, and the day and trial number had to be included due to the potential effects of fatigue. Before proceeding with any form of analysis of the three controlled variables, it was essential to consider each factor ad how it might affect potential results.

The first factor that was set as a block variable was the participant. Of all of the factors, participants influenced the most outcomes, as it was a significant factor in whether they wanted to use the exoskeleton again, their responses to how well the exoskeleton worked and its features, the changes in pain, and changes in muscle activation. The only category that the participant factor did not seem to influence was differences in cognitive and dexterity tests. These differences are well explained and make sense, as each influenced outcome highly depends on the person reporting/performing them. Considering most of the responses that participants made regarding the exoskeleton were purely subjective and just their impressions of the exoskeleton itself, it was not a surprise to see that each participant had a different opinion on the matter. These natural differences between participants are expected, and if participants were not a significant factor in these outcomes, it might be even more concerning, considering these are purely subjective metrics.

On the other hand, even the more objective differences appeared to be influenced by participants, namely the percent muscle activation and the changes in pain. The differences in percent muscle activation also make sense from a physiological standpoint; each participant will be able to exert different MVCs, and they also have physical differences that might have made these tasks more or less difficult for them versus a different participant. Additionally, there were many outcomes where participants influenced their differences in pain levels. Each person will have different pain tolerances, and differences in pain levels can mean completely different things from one person to the next. Psychological or physiological differences can be attributed to these differences, but significant differences should exist when comparing participants. Similar to the subjective outcomes that would naturally be influenced by the participants, there should also be inherent, built-in differences between participants, so seeing that participants are a significant factor can be used more as a way of validating the results than as a serious issue to be considered.

The effects of the trial and day numbers were the other factors that were not necessarily controlled for but were considered. In both cases, they had to be considered as there was the potential for fatigue to carry over from trial to trial or day to day. In looking at the statistical significance of either trial or day numbers' effects on any of the factors, though, there were conflicting results. For many of the results that indicated that one of those factors might play a role, bivariate linear fit models between that outcome and either the day or the trial number were not statistically significant. Even when they were, there was sometimes conflicting evidence; this was most apparent in the differences in reported neck pain versus the percentage of muscle activation of the splenius cervicis. Bivariate linear fit models for changes in neck pain led to smaller degrees of changes in neck pain on day two versus one, but on the other side, muscle

activation percentages of the splenius cervicis increased from day one to day two. This discrepancy can be explained in two ways: first, this was a statistically significant difference, and both are correct relationships. The increased muscle activity of the splenius cervicis may have just been a residual effect from the last couple of days, and the decrease in changes in neck pain is from participants being more mentally prepared as they knew more of what to expect the second day. Second, this may be statistically significant but is ultimately not practically important. The magnitude of the changes in neck pain when comparing the trial and day numbers was small (on the order of 0.1) relative to a scale asking participants to evaluate their pain from zero to ten. Additionally, for the percent muscle activation, there were two sensors evaluating the overall fatigue in the neck, but the fact that there was only a residual effect in one of the two neck muscles seemed abnormal. If the percentage of muscle activation was significantly affected by any residual fatigue from the first day to the second day, it would make sense if both muscles had a residual effect. However, this was not the case, as only one of the muscles demonstrated an increase in muscle activation. This may be because the splenius cervicis did have some amount of leftover fatigue, but it was considered negligible considering the splenius capitis was unaffected, and the magnitudes in the changes in muscle activation appeared to be minimal.

Additionally, the differences between the 45 and 90-degree postures were included, as it was naturally expected that a 90-degree posture would be more demanding than a 45-degree posture. It was shown that holding the 90-degree posture would increase the overall percent muscle activation of the erector spinae, change in neck pain, change in overall pain, and the rate at which pain changes. These were the expected and desired results, as the 90-degree posture was selected because it would allow for the greatest degrees of discomfort and muscle activation in the short 20- minute span designated for each trial. These data provide evidence that this

hypothesis worked and was effective in having a factor that would help accelerate the discomfort that participants were in, allowing for a wider range of discomfort levels to be tested than had it just been holding a 45-degree posture.

Subjective Opinions of the Exoskeleton

Regardless of an exoskeleton's objective benefits, the technology will ultimately not be used if participants have an unfavorable impression of it. As a result, participants were asked a few questions related to the usability of the exoskeleton and the effectiveness of the features involved with the exoskeleton. Arguably the most critical question was whether participants would use the exoskeleton again if they had the choice; if participants had answered no regardless, then the exoskeleton would never be used no matter how useful it was. Responses to this question revealed a strong, statistically significant relationship between participants' responses with the activation of the exoskeleton, which was also considered the control or experimental aspects of the exoskeleton as it decided if any forces were applied or not. Of the deactivated exoskeleton trials, 85% of responses stated that they would not use the exoskeleton if there were no assistive forces. On the other hand, when the exoskeleton was activated (forces were used to support participants), 75% of participants stated that they would use the exoskeleton again. This massive difference was indicative of the generally favorable opinions held by the participants of the exoskeleton when it was working and an unfavorable opinion of it when it was not. As long as the forces are appropriately set, and the participant feels like they are being supported, this study indicates that participants would at least be in favor of using them.

The favorable opinion of exoskeletons can be further analyzed by observing the subjective evaluations of the exoskeleton after the study concluded. Participants were asked to rate their experience of the exoskeleton and its various features using a 7-Point Likert Scale.

Participants stated that when performing this task of holding a static posture for extended periods, there were either no effects or positive benefits to participants. The exoskeleton did not lead to any differences in the frustration of performing the task, the movement involved, and the ability to complete the PPT or SDMT successfully, but participants agreed that it helped decrease the physical demands of the task, and they agreed that they would use it again. The benefits and lack of perceived negative impacts on participants' performances suggested that this exoskeleton could be treated as a viable option and supported the evidence that participants were likely to report wanting to use the exoskeleton again. If the exoskeleton was shown to be particularly harmful in one area or not at all beneficial, the likelihood of participants saying that they would use the exoskeleton again would decrease drastically, as seen when comparing the activated versus deactivated versions of the exoskeleton.

The usefulness of the individual aspects of the exoskeleton and their impacts on the exoskeleton's usefulness can be further analyzed by looking at the questions that participants were asked after each trial. Participants were again to evaluate their experience and rate the exoskeleton's potential alleviation of discomfort, the overall comfort of the exoskeleton, and their self-perceived ability to perform the cognitive tasks. While similar to the questionnaire asked at the end of the study, by asking participants these questions after each trial, individual factors and their effects could be further studied. This analysis provided further evidence of the importance of the activation status of the exoskeleton, as it led to decreased discomfort levels, increases in the comfort of the exoskeleton itself, and improvements in the self-perceived ability to complete the cognitive test. These differences were greatest in the alleviation of discomfort, as participants went from stating that the exoskeleton did not alleviate discomfort (zero is no help, ten is the most help possible) when deactivated (least squares mean = 1.5283) to significantly

alleviating discomfort when activated (least squares mean = 6.8050). Naturally, these results make sense and are further evidence of the usefulness of the exoskeleton. Additionally, there was a slight improvement in the comfort (zero is extremely uncomfortable, and ten is extremely comfortable) of the exoskeleton, regardless of the material, as it went from a least square mean of 2.9845 when activated to 5.5155 when activated. Both evaluations and their results were consistent with reports at the end of the study, where participants stated that the exoskeleton could be useful and not be uncomfortable, but there had to be the correct features in place first.

The final improvement in comparing the activation levels of the exoskeleton was in comparing the ability to complete cognitive tasks (zero is unable to perform simple cognitive tasks, and ten is performing at a normal ability). Without the activation, the self-evaluation of cognitive performance had a least square means value of 7.6122, but when activated, this increased to 8.2003. Though not as drastic a difference as the other two properties, this slightly conflicted with participants' responses regarding the question about their ability to perform the SDMT when they stated that the exoskeleton did not change their performance. This difference may be because, in the post-trial questionnaire, cognitive ability was asked about generally, while, in the post-study questionnaire, only the SDMT was asked about, which would only require a specific subset of cognitive performance. Furthermore, even if there were not huge differences between these categories, the increase from 7.6122 to 8.2003 is not a drastic change, so there might not be any practical significance between the two groups. Regardless, it was shown that there would at least be a slight, self-perceived improvement or no change relative to when it was not activated.

Objective Effects of the Exoskeleton

Subjectively, participants agreed that when activated, the exoskeleton either did not lead to any changes or positively affected their abilities to complete the tasks. More objective metrics of the effectiveness of the exoskeleton can also be analyzed to determine whether these metrics were also consistent with their subjective evaluations. The three primary objective metrics that were used were the percent muscle activation, the changes in pain (though inherently subjective as pain is based on individual perceptions, this was treated as an objective measurement because it was not directly assessing the exoskeleton itself, thereby reducing the risk of bias for or against a certain factor), and changes in the results of the PPT and SDMT.

Analysis of changes in the percent muscle activations and changes in pain go hand in hand as both assess the physical responses to using the exoskeleton. Theoretically, a decrease in the percent muscle activation (at least past a certain threshold) would decrease changes in pain. Results demonstrated that there were significant differences between activation levels for the percent muscle activations for all three muscles and the changes in pain for the neck, upper back, lower back, left shoulder, rate of change in pain over time, and the change in overall pain. In every single case, the deactivated version of the exoskeleton was more physically demanding (either requiring higher levels of muscle activation or increased changes in pain) than the activated version. When looking at the least square means for each case, the use of the activated exoskeleton caused about a 10% reduction in the muscle activations of the splenius capitis and splenius cervicis and a 4% reduction in the erector spinae. These decreases in muscle activation were further reflected in the changes in pain, as in each body part, there was approximately double the magnitude of the change in pain when going from the deactivated version to the activated version. Additionally, the activation of the exoskeleton also led to lesser changes in

pain and a decrease in the rate of pain developing over time. These results further support the subjective evaluations, which demonstrated that activation of an exoskeleton was a valuable tool in alleviating demand placed on the human body. These findings are unsurprising as the metrics of percent muscle activation, perception of usefulness in reducing the demand, and the perceived changes in pain will all correlate with one another.

The final objective measurements were the PPT and SDMT, which evaluated cognitive performance and dexterity, respectively, and took the change in performance from the start of each trial to the end. No statistically significant results were found, which was consistent with previous findings. Participants had stated that the exoskeleton neither helped nor hurt performance on either test, but there was a slight increase in perceived cognitive abilities when having the exoskeleton activated versus not. The lack of findings here may be explained by the tests selected; each test lasted either thirty seconds or one minute long, and speed was crucial in both tasks. In considering the brevity of the tasks, it is unsurprising to see that there were minimal differences between tests done at the beginning versus the end; if any factors were influencing their results, it was not nearly enough to be visible over a twenty-minute interval. Additionally, two tasks were performed, which individually assessed cognition and dexterity, but both were not analyzed simultaneously. Compared with surgeries that can last hours and require high levels of cognitive and dexterity abilities simultaneously, these short tests performed over twenty minutes were much too simplified to say whether surgeons' performances would be impacted accurately. However, the perceived improvements in cognitive ability indicated a relationship might exist, but it would require more appropriate tests performed over more extended periods. Previous literature has already outlined that there is a negative correlation between discomfort levels and cognitive attentional performances, so it would be unsurprising to

see if activation of the exoskeleton also led to an improvement in cognitive performances, as it has already been shown to reduce changes in pain, muscle activations, and perceived demands. Future studies should be performed studying this relationship.

Materials' Impacts

While studying the impacts of the exoskeleton and whether it helped reduce changes in pain, another factor studied was the materials chosen and whether they affected any outcomes. Participants demonstrated clear preferences for material selections, with the HD foam being the most favorable and the PE foam being the least favorable overall and in terms of comfort. It did not appear that temperature control was as significant as a factor in overall rankings, which was further reflected in the rankings of the overall properties as it was rated as the least important factor. Though only three materials were selected, there did appear to be a correlation between the softness and malleability of the material with each material's ranking. HD foam was the softness and most malleable, while PE foam was the most rigid. Many comments regarding this relationship were mentioned to the researchers and in the questionnaires asking participants to elaborate on previous answers. Some participants even requested that the HD foam be used for the entire exoskeleton headpiece and specifically requested that the PE foam not be used. Though not necessarily a factor that affected the overall perception of the exoskeleton, these apparent differences still outlined that preferences still existed among participants and that selection of the material should still be carefully considered.

Other than just the perceived rankings of the materials selected, the material selection did impact some objective metrics, specifically, the change in pain. By itself, the material selection was only significant in its effects on the change in overall pain. Results revealed that the selection of the HD foam led to significantly less change in pain throughout a trial than the other

two foams. Though not an individual body part, this decrease in the overall pain felt by participants was fascinating, as it indicated that even though participants did not say that the material selection was a crucial factor to consider, optimization could still contribute to improvements in the exoskeleton. Additionally, interaction effects told the same story: when an optimal material was selected or not, its effects compounded with other factors could impact the changes in pain experienced throughout trials. This was best illustrated by the combinations of the 90-degree posture with the deactivated exoskeleton and either the PE or neoprene foams and their impacts on upper back pain, which led to least squares means of 2.5412 and 2.4948, respectively. These levels individually were considered the least favorable (and neoprene foam was the second least favorable foam) in terms of both subjective and objective evaluations. Conversely, the 45-degree posture with the activated exoskeleton and the HD foam was the most favorable, leading to the least squares mean change in upper back pain of 0.4434. The stark contrast in the differences in changes in pain between these interactions demonstrated the potential for optimization, including the material, of the exoskeleton and its usefulness. Again, though not necessarily considered subjectively to be an essential feature relative to other factors, such as the activation of the exoskeleton, when carefully considered, its effects can still be impactful.

Limitations and Future Works

There were a few key limitations in this study that may limit the generalization and potential further implementation of exoskeletons in the operating room: first, the limited sample size from a young population. A total of eight participants successfully completed the study; these participants were all college students and were young, especially relative to the average age of a surgeon, and none practiced surgery. As a result, these participants can not directly vouch

for the usefulness of this exoskeleton in the operating room and may not even perceive changes in pain in the same way that surgeons do, as surgeons might be more accustomed to holding these static postures than these students. However, in considering the strong evidence for the use of the activated exoskeleton supported by both subjective and objective evaluations, though not surgeons themselves, there is reasonable evidence that this technology can be a useful tool for surgeons and a potential way to decrease MSDs.

Second, the apparatus created was not technically an exoskeleton but merely simulated the effects of an exoskeleton. Despite being referred to as an exoskeleton throughout this paper, the apparatus itself would not have been classified as an exoskeleton as it was fixed to the ground and not wearable like traditional exoskeletons. The researchers decided to replicate the system so that the amount of force used by participants could be recorded and so that the researchers could directly control the forces interacting with the exoskeleton. In pre-made exoskeletons, there often are dynamic forces supporting the body through the use of hydraulics or springs. Because participants were supposed to hold static postures, the researchers elected to use a system that could exert fixed, static forces through tension. This design would have to be recreated and condensed into a wearable object, but the concept would remain the same: the exoskeleton would exert a fixed, static force at specific postures to support participants' bodies.

Third, the exoskeleton was still used in the deactivated group as a way to evaluate the effectiveness of the exoskeleton system. On paper, this study was set up to be blinded, meaning participants would not know whether the exoskeleton was activated. While this may have worked in theory if trials were truly independent and did not remember their past experiences with the exoskeleton, participants quickly recognized the difference between activated and deactivated. The lack of blinding may have led to potential biases in favor of the exoskeleton

during the subjective evaluations or decreases in perceived changes in pain. However, the subjective evaluations did not appear to be significantly influenced by the activation, as shown through the objective metrics of a decrease in muscle activation. Considering all three muscles had lower activation percentages, it was unsurprising that participants had lower perceived pain levels and generally more favorable impressions of the exoskeleton when it was activated. With that being said, the use of the exoskeleton headpiece, while deactivated, may have negatively impacted participants due to its additional weight at the front of the head. The extra weight was kept as it would lead to greater degrees of fatigue within twenty minutes while also simulating the use of a surgical headlamp.

The final primary limitation of this study is the trial length and the tests performed. Surgeries can last hours on end, but this study only had participants stand in a static posture for twenty minutes, meaning the full effects of fatigue were not seen. To counteract the difference in length, participants were asked to hold a static posture without moving or stretching and have the additional weight from the headlamps on their heads. These adjustments made the task more challenging, so more significant effects of fatigue could be seen. Despite this brevity, significant findings demonstrating that activation of the exoskeleton was beneficial were still seen. Considering that fatigue would only increase over time, there was nothing to indicate that further use of the exoskeleton would lead to a change in the pattern of reducing the percent muscle activation or the changes in pain.

Conclusion

Surgeons are in need of techniques and technologies that can help reduce the risk of them developing MSDs. In this study, the effects of the activation of an exoskeleton, posture, and materials on opinions of the exoskeleton and its features, changes in pain, changes in muscle

activation percentages, and changes in cognitive and dexterity performances were studied. Activation of the exoskeleton led to decreases in the changes in pain experienced by participants and decreases in the percent muscle activations while also leading to reported improved cognitive performances. Participants also reported clear preferences for the material used, which could lead to decreased overall pain levels when optimized. Most participants expressed favorable impressions of the exoskeleton, stating that they would use it again as long as the system was activated. These results show that exoskeleton may be a useful technology in not only the decrease in the likelihood of developing MSDs and decreasing the pain associated with performing surgeries but also a potential increase in surgical performances due to both of these benefits.

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Appendix A. Surveys and Additional Statistical Analysis

1. Please rate your discomfort of the following body parts right now on a scale of 0 to 10 with zero being no pain and ten being the worst pain possible.

a. Head (physical):	0	1	2	3	4	5	6	7	8	9	10
b. Head (mental, i.e. headaches):	0	1	2	3	4	5	6	7	8	9	10
c. Neck:	0	1	2	3	4	5	6	7	8	9	10
d. Upper Back:	0	1	2	3	4	5	6	7	8	9	10
e. Lower Back:	0	1	2	3	4	5	6	7	8	9	10
f. Left Shoulder:	0	1	2	3	4	5	6	7	8	9	10
g. Right Shoulder:	0	1	2	3	4	5	6	7	8	9	10

h. Please describe any other pain or fatigue that you may have:

_____

_____

_____

_____

Figure A1. Questionnaire Used for the Pre-Day, Pre-Trial, Post-Trial, and Post-Day Evaluations

1. On a scale of 0 to 10, please rate the degree to which the exoskeleton helped alleviate any head, neck, or back discomfort with zero being no help and ten being the most help possible:

   0 1 2 3 4 5 6 7 8 9 10

2. On a scale of 0 to 10, please rate the comfort/discomfort of the exoskeleton with zero being extremely uncomfortable, five being neither comfortable nor uncomfortable, and ten being extremely comfortable:

   0 1 2 3 4 5 6 7 8 9 10

3. On a scale of 0 to 10, please rate the heat of your forehead throughout the study with zero being a normal temperature and ten feeling like your forehead is burning:

   0 1 2 3 4 5 6 7 8 9 10

4. On a scale of 0 to 10, please rate the comfort/discomfort of the exoskeleton's forehead material with zero being extremely uncomfortable, five being neither comfortable nor uncomfortable, and ten being extremely comfortable:

   0 1 2 3 4 5 6 7 8 9 10

5. On a scale of 0 to 10, please rate the degree to which the exoskeleton's forehead material helped keep your head cooler/warmer than normal throughout the study with zero being uncomfortably cold, five being a normal temperature, and ten being uncomfortably hot:

   0 1 2 3 4 5 6 7 8 9 10

6. Which body parts did you feel the most discomfort? Please answer N/A if you felt no discomfort.

_____

_____

7. On a scale of 0 to 10, please rate the degree to which you could perform cognitive tasks with zero being unable to perform simple cognitive tasks and ten being able to perform as well cognitively as during a normal situation:

   0 1 2 3 4 5 6 7 8 9 10

8. If you had the option to use this exoskeleton again if this study was repeated?

   Yes No

9. Please elaborate on your answer to Question 8: _____

_____

_____

Figure A2. Post-Trial Questionnaire

Head and Neck Exoskeleton - Data Collection Form for Researcher

This data collection form should be used for three trials with one type of material.

Participant ID: _____ **Date:** _____

Day # (circle one): 1 2

Pain Scale:

Record the pain of participants from 0 to 10 with zero being no pain and ten being the worst pain possible. Pain will be recorded by verbally asking participants what their pain is every two minutes.

Order #:				
Material				
Control or experimental				
Posture	**___ Degree Angle**		**___ Degree Angle**	
Time (mins)	**Pain**	**Force**	**Pain**	**Force**
0				
1 – SDMT				
2				
3 – PPT (RH)				
3 – PPT (LH)				
3 – PPT (R+L)				
3 – PPT (Asbl)				
4				
6				
8				
10				
12				
14				
15 – PPT (RH)				
15 – PPT (LH)				
15 – PPT (R+L)				
15 – PPT (Asbl)				
16				
18				
18 – SDMT				
20				

Figure A3. Data Collection Form for Recording Pain, SDMT Results, PPT Results, and Forces

Head and Neck Exoskeleton – Post-Study Survey

This survey should be administered to participants at the end of the study. This will be after the participant has finished all trials.

Participant ID: _____ **Date:** _____

1. Please rate your preference for the materials that you used with 1 being the best material and 3 being the worst:

Material A: _____
Material B: _____
Material C: _____

2. Please rate the comfort of the materials that you used with 1 being the most comfortable material and 3 being the least comfortable material:

Material A: _____
Material B: _____
Material C: _____

3. Please rate the degree to which the materials that your forehead at an ideal temperature with 1 being the best material for temperature control and 3 being the worst material for temperature control:

Material A: _____
Material B: _____
Material C: _____

4. Please rate the following characteristics of the exoskeleton in terms of importance relative to usability with 1 being the most important to consider and being the least important to consider:

Temperature control, softness of the forehead material, force exerted by the exoskeleton

Temperature Control: _____
Softness of the Forehead Material: _____
Force Exerted by the Exoskeleton: _____
Frustration Caused by the Exoskeleton: _____

Please select the response that best aligns with your opinion of using the exoskleton:

5. If I performed a task requiring looking down for long periods of time, I would use this exoskeleton.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

6. The exoskeleton made my job less physically demanding than if I were not wearing it.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

7. I became frustrated using the exoskeleton.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

8. I was able to move well with the exoskeleton on.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

9. I had difficulty interacting with my work environment and the tasks at hand.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

10. I felt like using the exoskeleton improved my ability to complete the Purdue Pegboard Dexterity task.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
						

11. I felt like using the exoskeleton improved my ability to complete the Symbol Digit Modalities Test.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
						

12. What features of the exoskeleton did you like and/or think were useful?

13. What features of the exoskeleton did you not like and/or think were unhelpful?

14. What changes would you make to the exoskeleton to make it more usable?

15. What changes would you make to the exoskeleton to make it more comfortable?

Figure A4. Post Study Questionnaire

Symbol Digit Modalities Test #1 (SDMT)

∑	┼	∂	ω	∏	∓	∔	♣	♠
1	2	3	4	5	6	7	8	9

∑	∓	∔	ω	∏	♠	∑	♠	┼	♠

♠	┼	ω	ω	┼	ω	∏	ω	∏	∏

∔	♠	∏	∓	∂	∏	∓	∏	∔	∂

♣	∑	♣	∂	┼	∂	∔	∑	∂	∑

♠	∓	∑	∔	∑	♣	ω	∂	ω	♠

┼	♣	♠	♣	♣	∔	∔	∂	┼	∓

∑	∓	∏	┼	∂	♣	∓	┼	∓	♣

Figure A5. Example of the Symbol Digit Modalities Test

Figure A6. Picture of the Purdue Pegboard Test

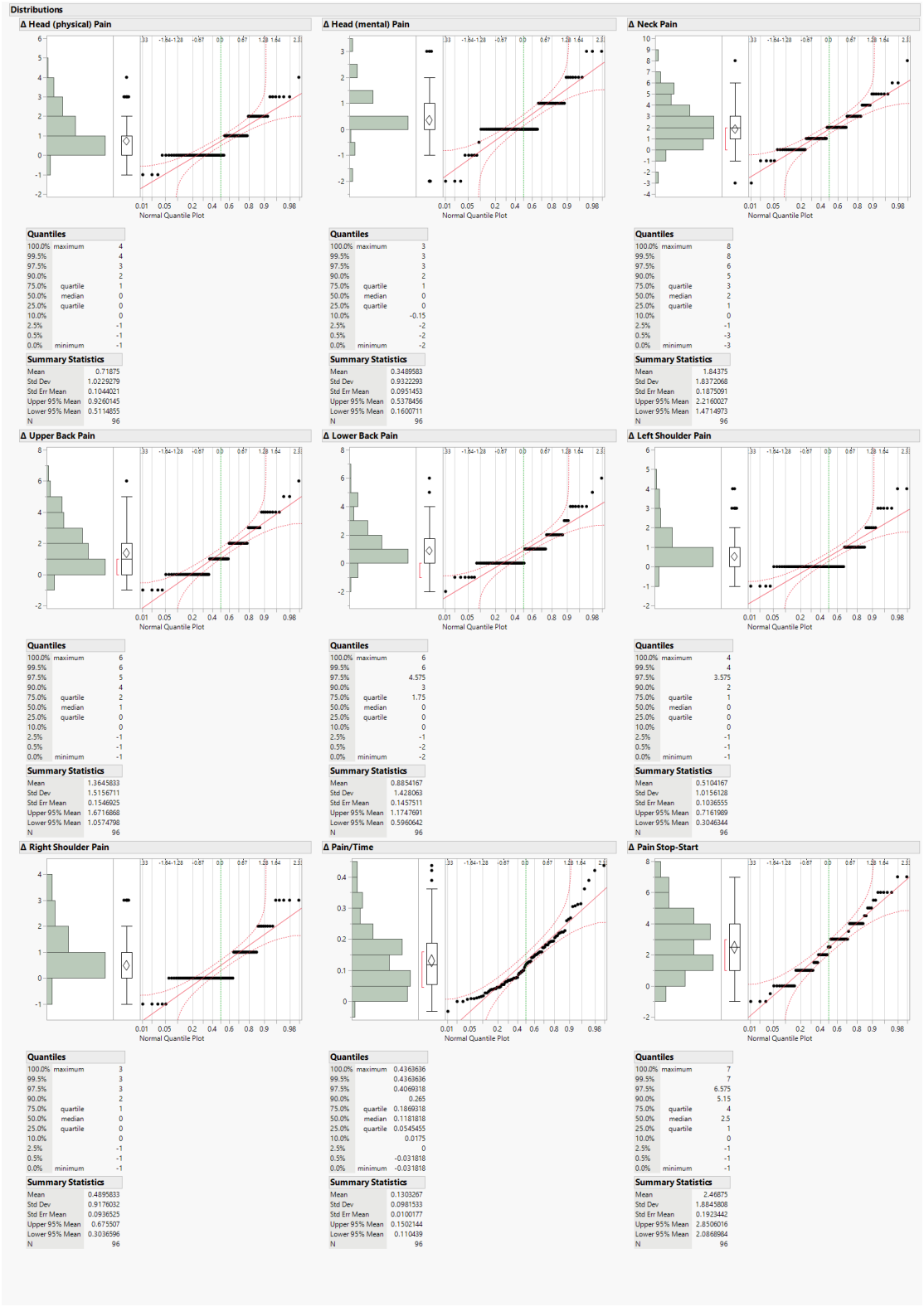


Figure A7. Normality Quantile Plots of Changes in Pain During Trials

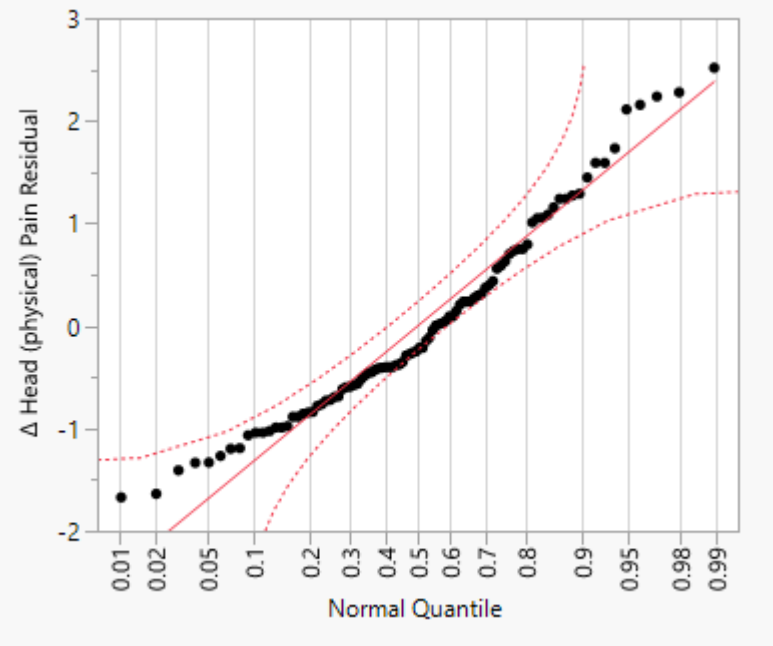
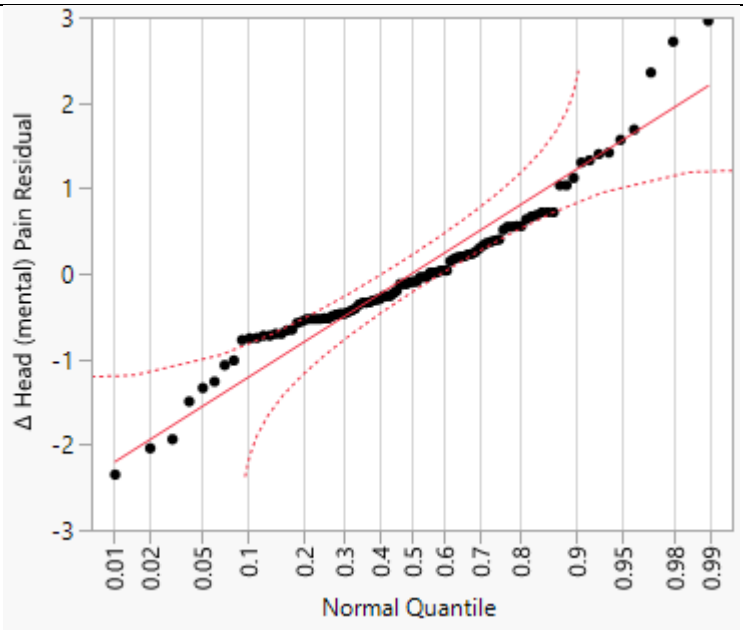
Source	Normal Quantile Residual Plots
Δ Head (physical) Pain	
Δ Head (mental) Pain	

Figure A8. Residual Normal Quantile Plots for Changes in Pain During Trials

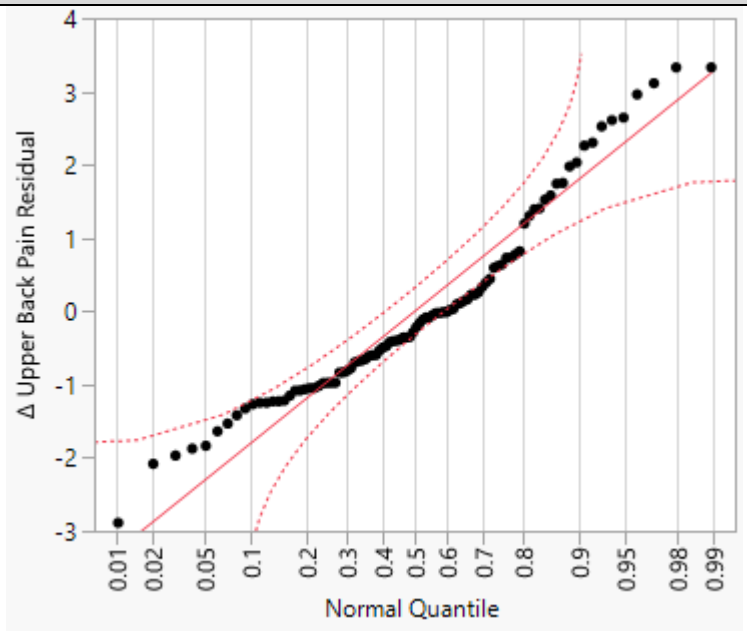
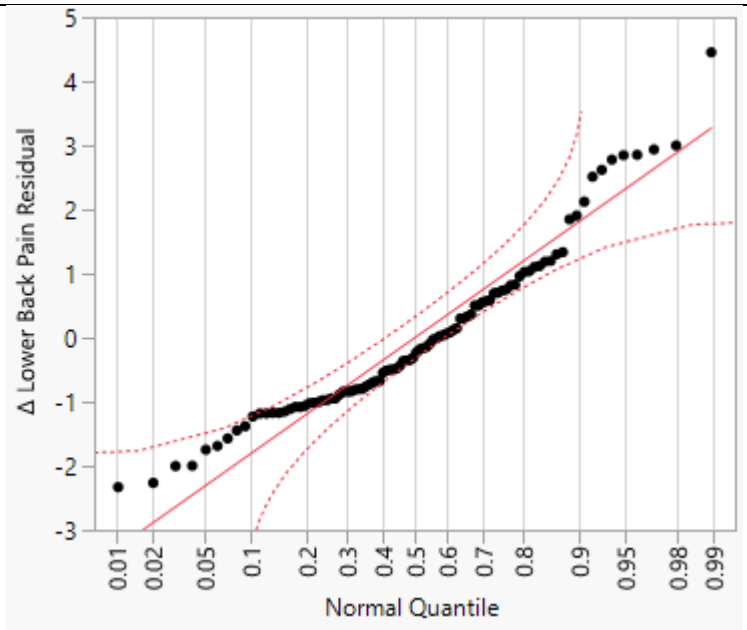
Source	Normal Quantile Residual Plots
Δ Upper Back Pain	
Δ Lower Back Pain	

Figure A8 (cont.). Residual Normal Quantile Plots for Changes in Pain During Trials

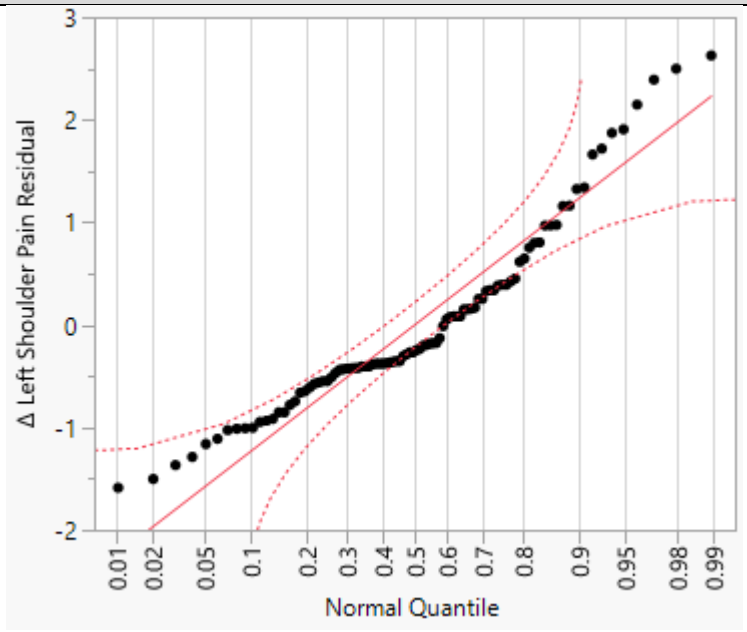
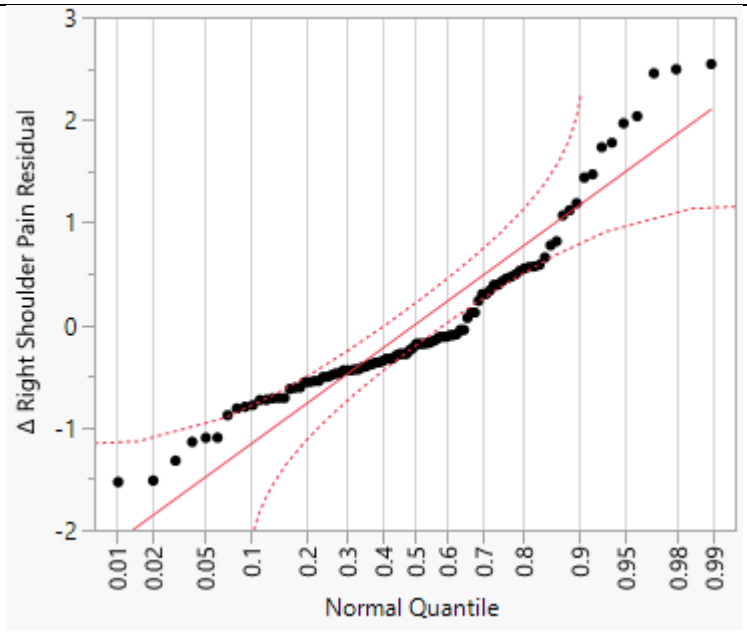
Source	Normal Quantile Residual Plots
Δ Left Shoulder Pain	
Δ Right Shoulder Pain	

Figure A8 (cont.). Residual Normal Quantile Plots for Changes in Pain During Trials

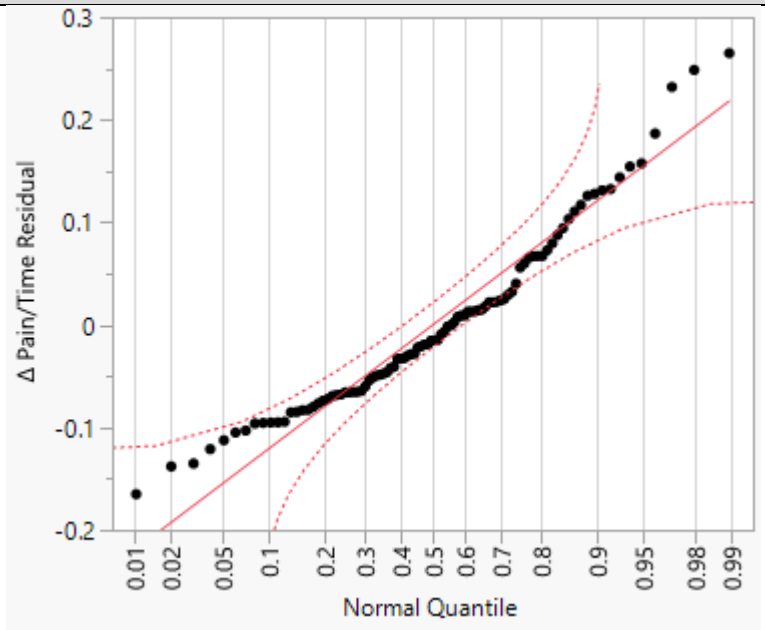
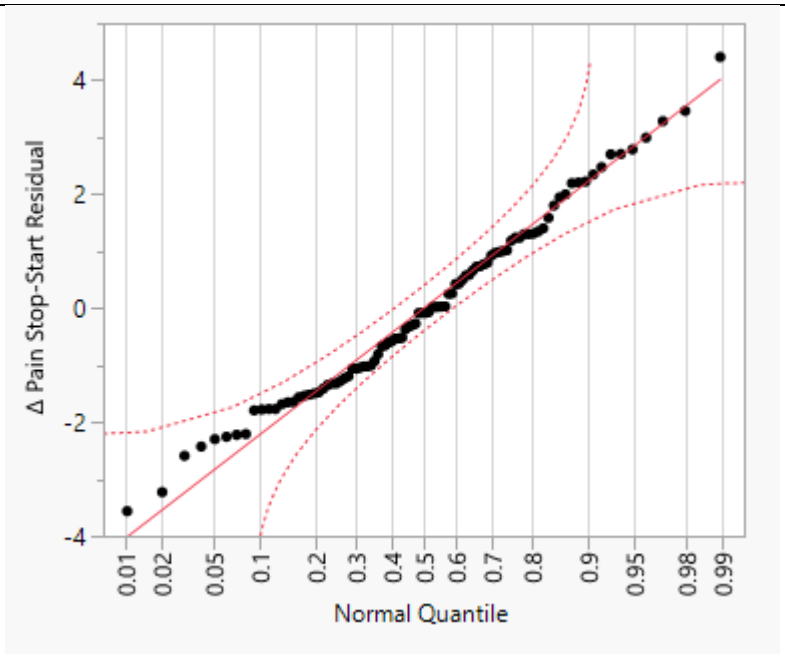
Source	Normal Quantile Residual Plots
Δ Pain/Time	
Δ Overall Pain	

Figure A8 (cont.). Residual Normal Quantile Plots for Changes in Pain During Trials

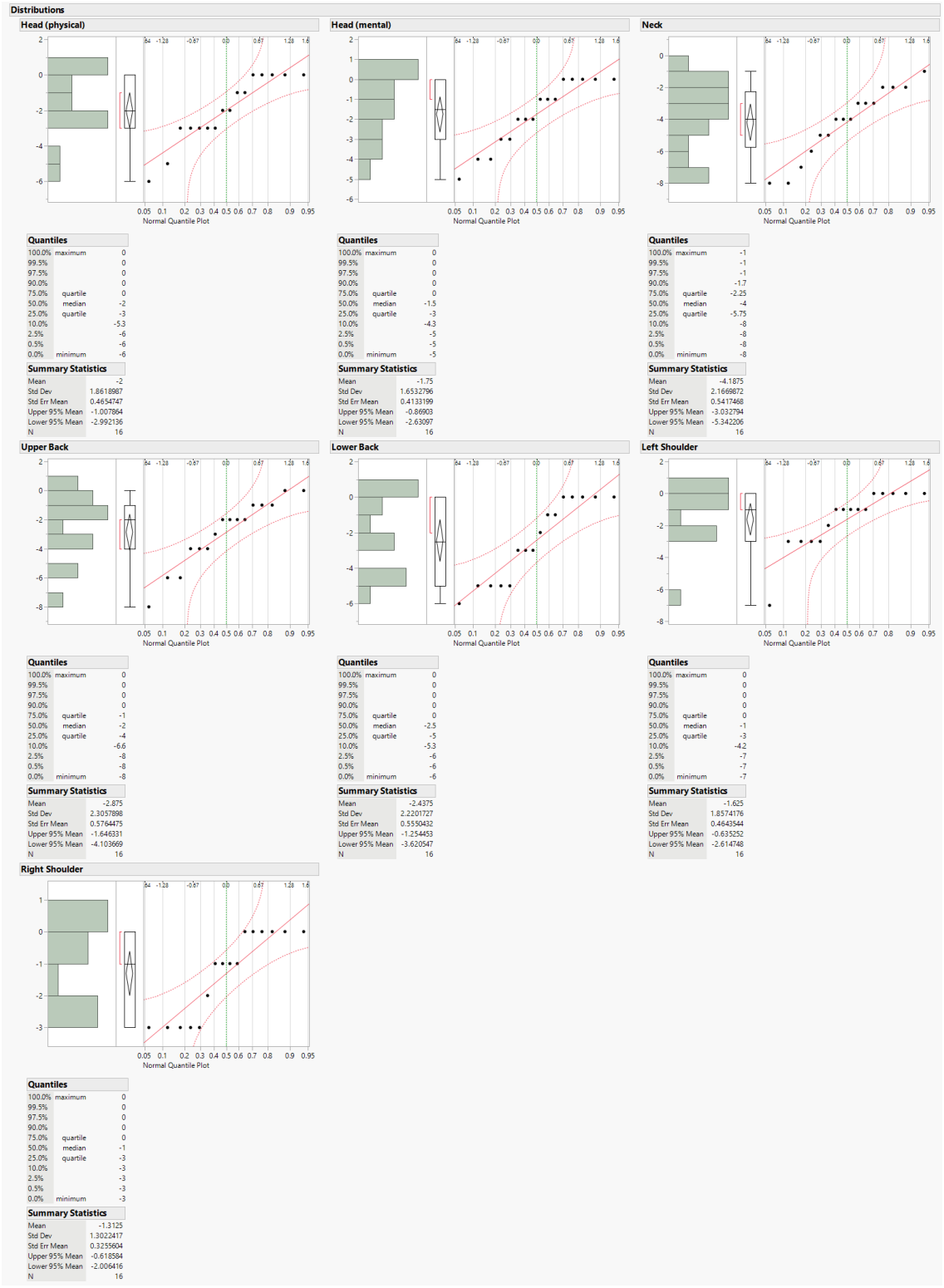


Figure A9. Normality Quantile Plots of Changes in Pain Throughout the Day

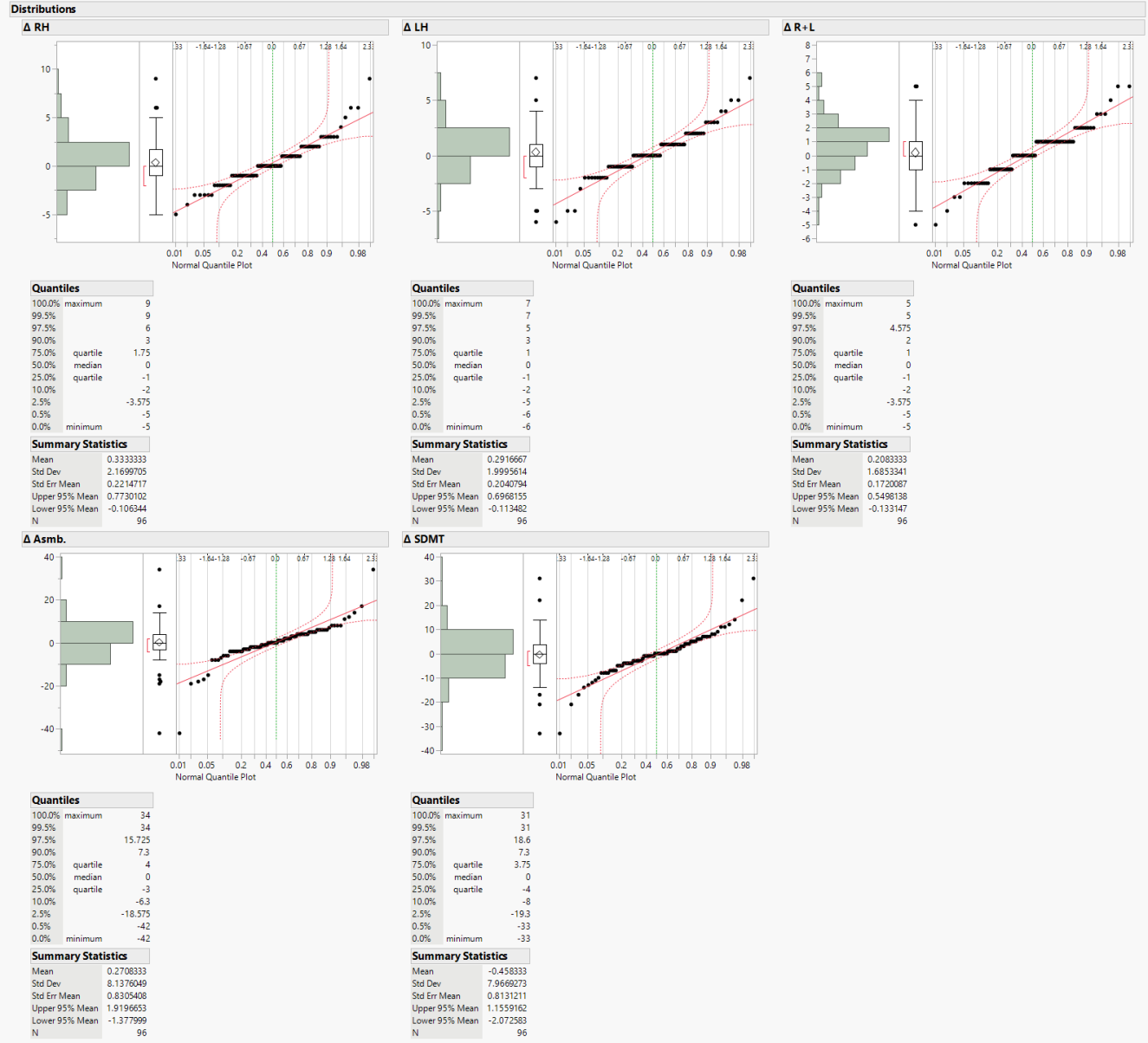


Figure A10. Normal Quantile Plots of Cognitive and Dexterity Tests

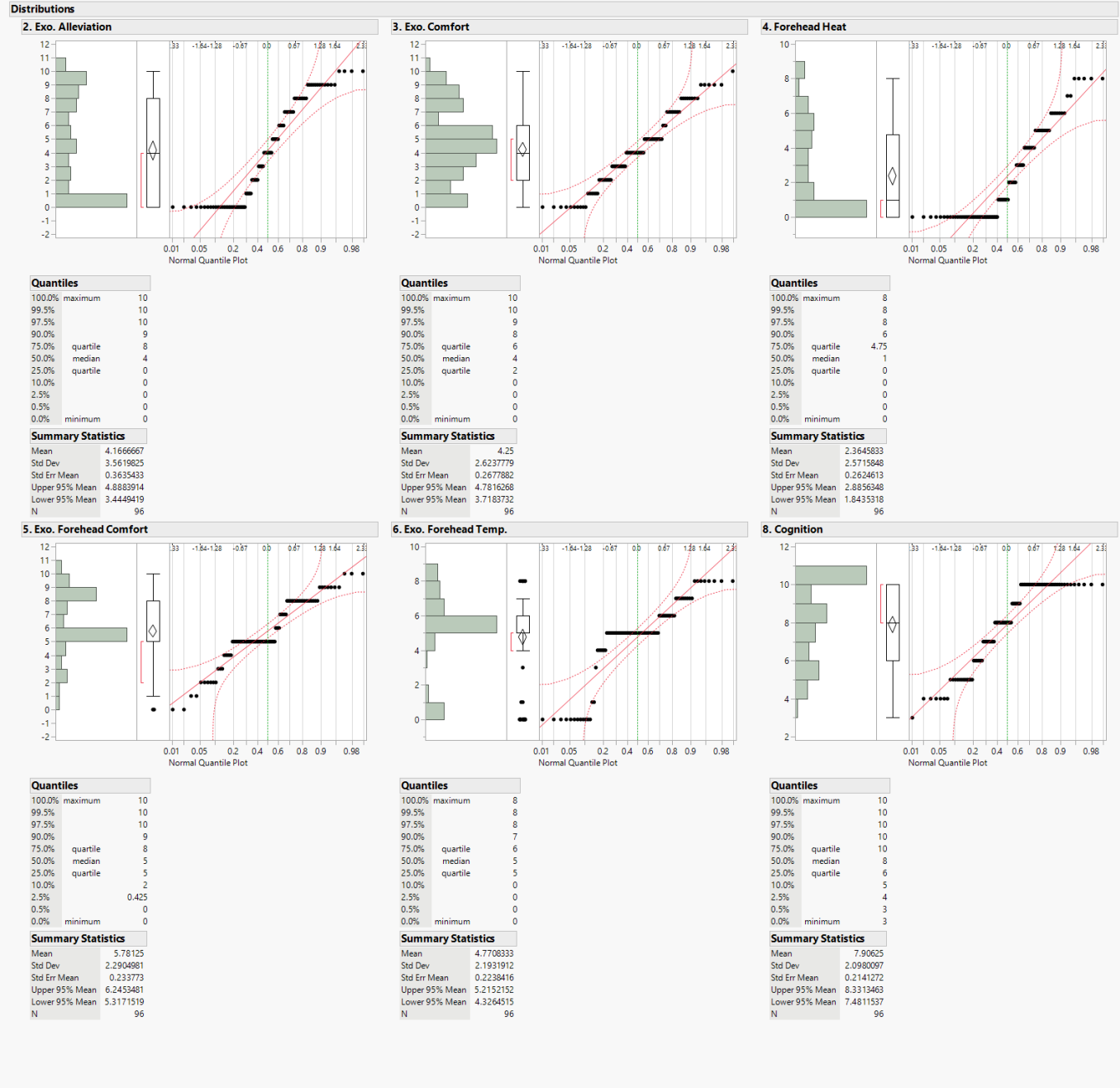


Figure A11. Normal Quantile Plots of Trial Evaluations

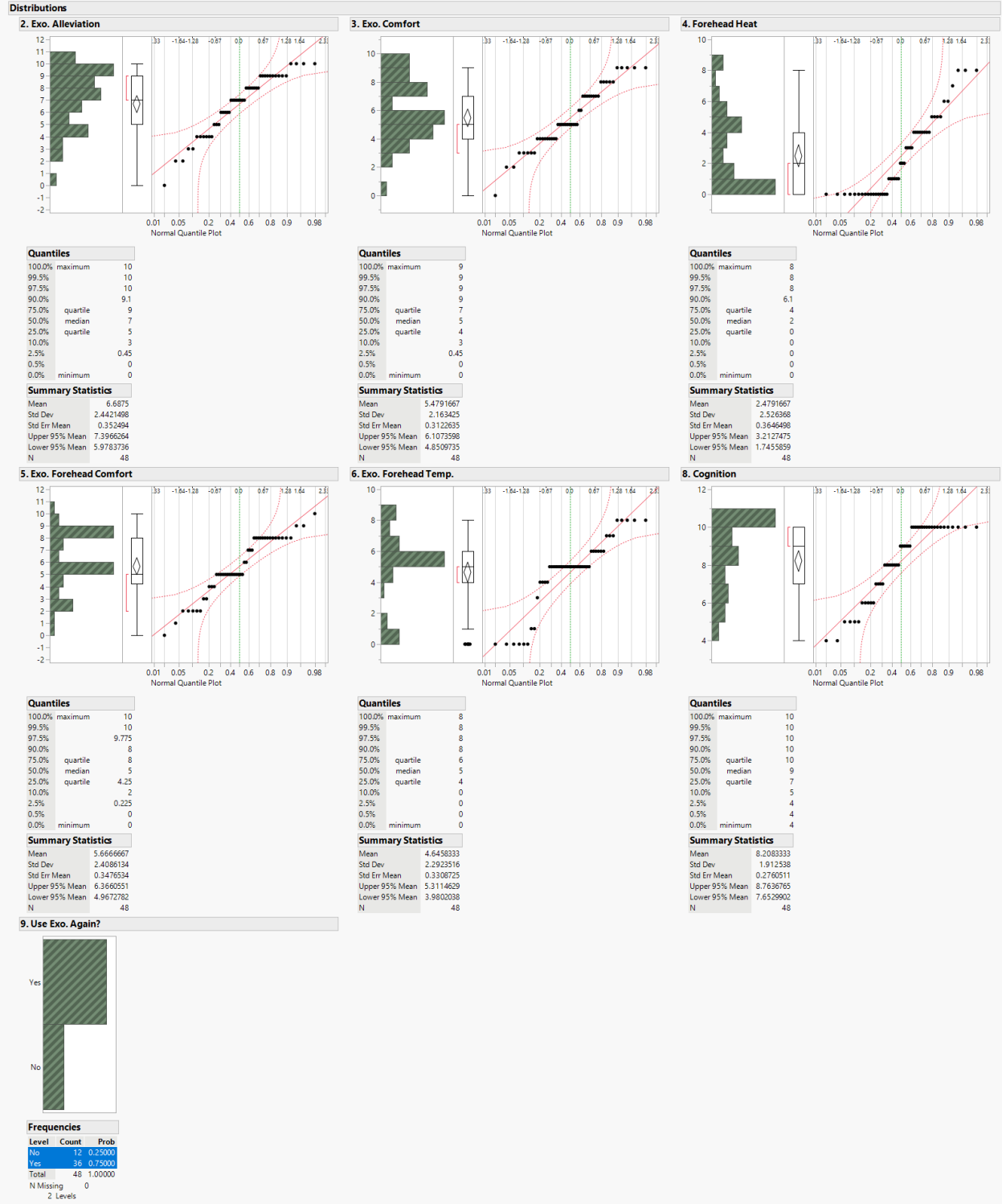


Figure A12. Normal Quantile Plots of Trial Evaluations – Only Activated Group

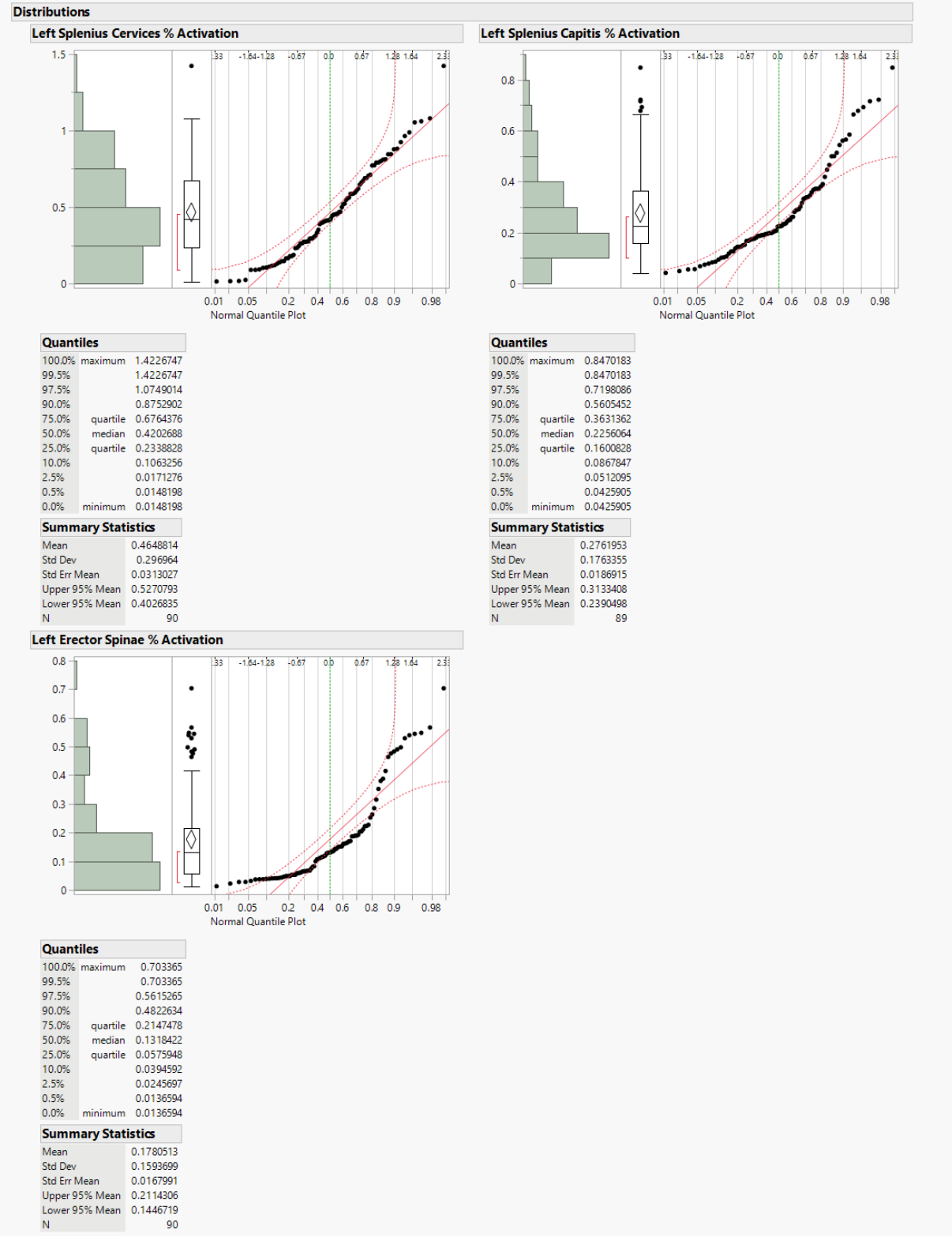


Figure A13. Normal Quantile Plots of Muscle Activations

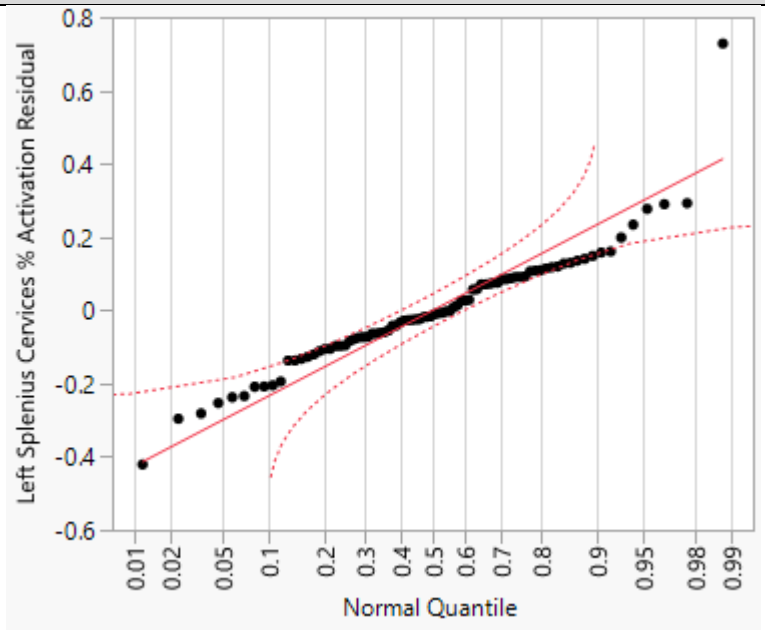
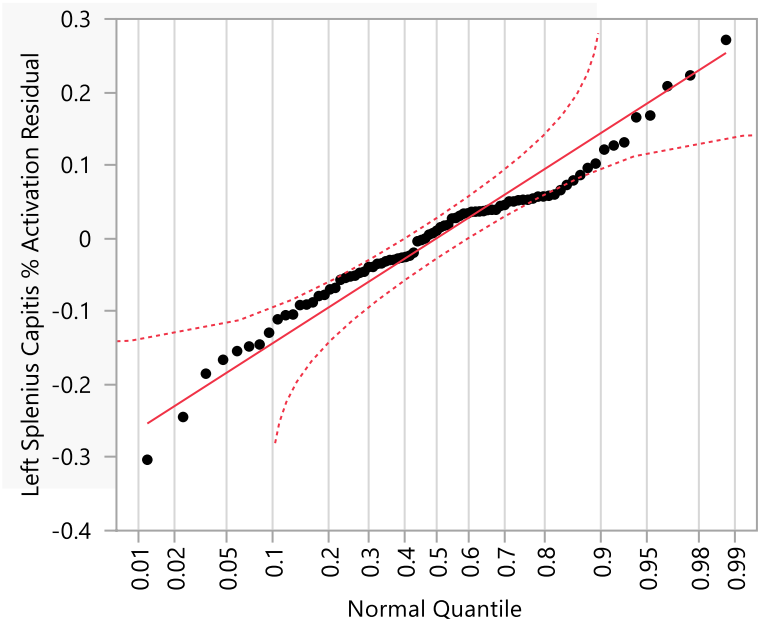
Source	Normal Quantile Residual Plots
Splenius Cervices % Activation	
Splenius Capitis % Activation	**Residual Normal Quantile Plot** 

Figure A14. Residual Normal Quantile Plots of Muscle Activations

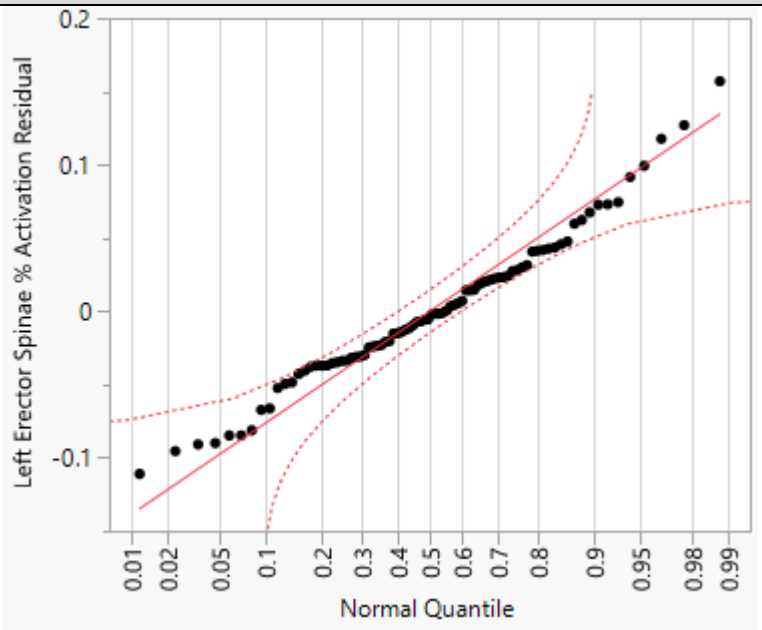
Source	Normal Quantile Residual Plots
Erector Spinae % Activation	

Figure A15 (cont.). Residual Normal Quantile Plots of Muscle Activations

Appendix B. Approval for Research (IRB)

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office of Research Ethics
Vice President for Research
2420 Lincoln Way, Suite 202
Ames, Iowa 50014
515 294-4566

Date: 10/06/2022

To: Richard T Stone

From: Office of Research Ethics

Title: Thermal Effects of Head and Neck Exoskeleton on Surgeon's Performances

IRB ID: 22-096

Submission Type: Modification **Review Type**: Expedited

Approval Date: 10/06/2022 **Approval Expiration Date:** N/A

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, including the **recruitment materials and informed consent documents that have the IRB approval stamp**.
- **Retain signed informed consent documents for 3 years after the close of the study,** when documented consent is required**.**
- **Obtain IRB approval prior to implementing any changes** to the study or study materials.
- **Promptly inform the IRB of any addition of or change in federal funding for this study.** Approval of the protocol referenced above applies only to funding sources that are specifically identified in the corresponding IRB application.
- **Inform the IRB if the Principal Investigator and/or Supervising Investigator end their role or involvement with the project** with sufficient time to allow an alternate PI/Supervising Investigator to assume oversight responsibility. Projects must have an eligible PI to remain open.
- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.
- IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g., student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of

Figure A16. IRB Approval Form

those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

- Your research study may be subject to **post-approval monitoring by Iowa State University's Office of Research Ethics**. In some cases, it may also be subject to formal audit or inspection by federal agencies and study sponsors.

- Upon completion of the project, transfer of IRB oversight to another IRB, or departure of the PI and/or Supervising Investigator, please initiate a Project Closure to officially close the project. For information on instances when a study may be closed, please refer to the IRB Study Closure Policy.

If your study requires continuing review, indicated by a specific Approval Expiration Date above, you should:

- **Stop all human subjects research activity if IRB approval lapses**, unless continuation is necessary to prevent harm to research participants. Human subjects research activity can resume once IRB approval is re-established.

- **Submit an application for Continuing Review** at least three to four weeks prior to the **Approval Expiration Date** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

IRB 07/2020

Figure A17 (cont.) IRB Approval Form

CHAPTER 4. GENERAL CONCLUSION

Exoskeletons are a promising and exciting novel tool in helping in the fight against MSDs, regardless of the industry. Current literature on surgical exoskeletons proved that there is a large gap between types of exoskeletons and their respective purposes, as active exoskeletons were almost exclusively for performance augmentation while passive exoskeletons were almost entirely focused on improved ergonomics. This discrepancy between the two sub-categories of exoskeletons has made some studies appear to have tested the exoskeleton one way or the other. However, if alternate purposes and outcomes are also considered, for example, ergonomic exoskeletons analyzing performance augmentation outcomes, it can provide a more powerful argument for why or how exoskeletons might be implemented in the future. This multifaceted approach considers usability, ergonomic features, and performance augmentation outcomes.

To test this multifaceted approach, an experiment was conducted with eight participants to test the effectiveness of a head and neck surgical exoskeleton apparatus. This test revealed that when the exoskeleton was activated, meaning that tension was enabled, participants displayed lower changes in pain, lower muscle activations in their splenius capitis and splenius cervicis, and erector spinae, and improved subjective metrics regarding the exoskeleton. Performance metrics, namely the Purdue Pegboard Test and the Symbol Digit Modalities Test, were also administered, but there were no significant differences from the start of the trial to the end. Finally, the high-density foam was rated the best and most comfortable overall. It was reported that when this foam was selected, it could potentially lead to a decrease in the overall change in pain. Though not technically an exoskeleton, the results and resultant forces are compelling evidence that using exoskeletons may reduce pain and decrease muscle activations experienced by surgeons.