The Design, Prototyping, and Validation of a New Wearable Sensor System for Monitoring Lumbar Spinal Motion in Daily Activities

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The Design, Prototyping, and Validation of a New Wearable Sensor System for Monitoring Lumbar Spinal Motion in Daily Activities

Brianna Bischoff

A thesis submitted to the faculty of Brigham Young University in partial fulfillment of the requirements for the degree of Master of Science

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Abstract

Lower back pain is a widespread problem affecting millions worldwide, because understanding its development and effective treatment remains challenging. Current treatment success is often evaluated using patient-reported outcomes, which tend to be qualitative and subjective in nature, making objective success measurement difficult. Wearable sensors can provide quantitative measurements, thereby helping physicians improve care for countless individuals around the world. These sensors also have the potential to provide longitudinal data on daily motion patterns, aiding in monitoring the progress of treatment plans for lower back pain. In this work it was hypothesized that a new wearable sensor garment that makes use of high-deflection strain gauge technology—called the Z-SPINE System—will be capable of collecting biomechanical information capable of detecting characteristics of motion associated with chronic lower back pain from subjects as compared to skin-adhered wearable sensor systems.

The initial prototyping development of the Z-SPINE System focused on optimizing the device’s conformity to the skin, as well as the ease of use and comfortability of the design. Preliminary motion capture tests concluded that a waist belt made of an elastic four way stretch material with silicone patches and no ribbing had the highest skin conformity of the garment types tested, and further design decisions were made utilizing this knowledge.

A human subject study was conducted with 30 subjects who performed 14 functional movements with both the Z-SPINE System, and the SPINE Sense System—a pre-existing wearable sensor system that utilizes the same high-deflection strain gauge technology and is adhered directly to the back. Multiple features were extracted from the strain sensor datasets for use in machine learning modeling, where the model was trained to distinguish the different movements from each other. The accuracy of the model was assessed using 4 different category number variations—two 4 category, one 7 category, and one 13 category variation. Four different machine learning models were used, with the random forest classifier generally performing the best, yielding prediction accuracies of 85.95% for the SPINE Sense System data, and 71.23% for the Z-SPINE System data in the 4 category tests.

As an additional part of the human subject study, the usability of the Z-SPINE System was also assessed. Each participant filled out a system usability scale questionnaire in regards to their opinion and experience with the system after having used it; the average score given by participants was 83.4, with general feedback consisting of positive remarks about the comfort and ease of use of the current design and suggestions for improving the battery placement and fit of the Z-SPINE system.

It is concluded that a machine learning model of the data from the Z-SPINE System can identify biomechanical motion with reasonable accuracy as compared to a skin-adhered wearable sensor system when the number of categories is limited. It is also concluded that the system is simple and intuitive to use.

Keywords: low back pain, high deflection strain gauges, system usability, biomechanics, product design, machine learning, cross-validation, sensors, and nanocomposite sensors.
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1 Introduction

Lower back pain is one of the most common health problems in the world, with hundreds of millions of people experiencing it. Unfortunately, information on how an individual develops chronic lower back pain is still sparse, and treatment of the condition can prove to be quite difficult. Often, the success of treatments is measured through patient-reported-outcome-measures (PROMs). PROMs tend to be qualitative and are highly subjective, so measuring the success of a treatment objectively can be difficult. Wearable sensors offer the potential to quantitatively measure objective outcomes, which can in turn be helpful in adjusting treatment plans and methods thereby helping people with chronic lower back pain reduce their pain levels. Similarly, wearable sensors in the spine allow for extended duration data collection of people’s daily motion patterns, aiding in monitoring the progress of treatment plans for lower back pain. The hypothesis of this research is that a new wearable nanocomposite sensing garment that is reusable, comfortable, and can be applied by the patient can accurately record the motion of the lumbar spine. The structure of the thesis is described below.

Chapter 2 outlines the background regarding the existing literature related to the thesis topics. In particular, works that detail the development and testing of other wearable sensor devices meant for spinal biomechanics monitoring. It provides a deeper understanding of the current technology and its benefits and uses for spinal monitoring, including applications towards lower back pain. Further information and previous work on a nanocomposite strain sensor array (the SPINE Sense System) is also discussed, with an emphasis on the device’s design, application, and use.

Chapter 3 presents the design and prototyping of the Z-SPINE System to document the process by which the final design was made. The Z-SPINE System makes use of the same sensors as the SPINE Sense System. In the SPINE Sense System, the sensors are fastened to athletic tape that is adhered to the skin; it is assumed that the success of the system in detecting characteristics of biomechanics is due to a high level of conformity of the sensor to the skin during human motion. Thus, conformity to skin strain is assumed to be of utmost importance in the design of the new device. In order to make sure the sensor system design has the highest skin conformity, three primary tests were run on different garment types: first with paint, then with optical motion capture. Analysis of the data collected indicated that a waist belt with silicone patches (that improve adhesion to the skin) and no ribbing or supports had the best skin conformity and would therefore serve as the best base garment design. It was determined that a removeable sensor array would be attached to the base garment for reusability purposes (making the garment washable, for example). Related design factors, such as the sensor piece attachment method, and the specifics of the electrical system are discussed. It was ultimately determined that a mixture of Velcro and metal clothing snaps would be used to attach the sensor piece to the waist belt, and that a 9V battery would be used as the power source.
Chapter 4 is a draft journal paper that will be submitted to a journal with co-authors being: Dr. David Fullwood, Dr. Anton Bowden, Dr. Ulrike Mitchell, and Tyler Hutchinson. This work was performed in the BABEL lab at Brigham Young University where a human subject test was conducted on 30 participants. Each participant had a SPINE Sense System array placed on their lower back and they were then instructed on how to perform 14 functional movements that encompass all three kinematic planes of motion. Resistance data was collected from the arrays while they performed these movements. Upon completion of these movements the SPINE Sense array was removed, and subjects were given instruction on how to put on the Z-SPINE System. Once the Z-SPINE System was applied, the subjects then repeated the same movements. Subjects then completed a survey using the system useability scale about the Z-SPINE System. The data from both arrays was processed and features were extracted to use several different machine learning models to classify different motion types. For the data from the SPINE Sense System, these models were able to achieve up to 85.95% prediction accuracy for a subcategory of four motion types; using the Z-SPINE data, up to 71.23% prediction accuracy was achieved. The results support the hypothesis that a garment-type sensor system that is not adhered to the back can achieve reasonable accuracy in terms of detecting key characteristics of human back biomechanics. The information from the System Useability Scale was analyzed, with the average score being 83.4, indicating that the Z-SPINE System is usable and intuitive to use.

Chapter 5 contains key conclusions from the research and identifies areas where further work and analysis could extend the results found in this thesis. It is concluded that the Z-SPINE System is capable of collecting classifiable biomechanical information from subjects (i.e. that a model can be developed from the data that enables classification of different movements) at a similar resolution as skin-adhered wearable sensor devices and that the system is capable of being easily and intuitively used. The Z-SPINE System could be used in the future to improve the standard of care for medical treatment concerning the spine, and thereby improve the lives of many people around the world. Future research should focus on expanding the cohort of subjects in order to prove that the biomechanical data collected by the Z-SPINE is not just classifiable but also of adequate quality to detect characteristics of motion associated with chronic lower back pain. Research could be conducted to decrease the variability across devices and improve the performance of the system itself, implementing the feedback from the System Useability Scale. Further research could be conducted to determine how the prediction accuracy is impacted by the number of sensors present, as such information could be of extreme benefit to future design iterations and manufacturing efforts; the importance of each individual sensor and their placement as well as the different features should also be investigated beyond what was conducted here to better understand what information the Z-SPINE should focus on collecting to more accurately track human motion.
2 Background

2.1 Low Back Pain

Most people experience some form of lower back pain at some point in their lives, making it one of the most common health problems in the world. [1] It is estimated that 80% of the global population will experience back pain in their lives, with lumbar spinal pathologies being up to 10 times more prevalent than those in other areas of the spine. [2-3] This condition, prevalent across all ages and genders, significantly impacts an individual’s daily life and ability to work. In the United States, lower back pain incurs hundreds of billions of dollars annually in direct and indirect costs, including but not limited to expenses related to the diagnosis and treatment of back pain.[4-7] The bulk of these costs are associated with the time and money lost from the inability to work while dealing with the ailment—which is unsurprising, as lower back pain has the highest disability-adjusted-life-year (DALY) among all debilitating conditions. The DALY is a combined measure of the years of life lost due to disability and premature death; the DALY for lower back pain has been tracked since 1990 and shows a distinct upward trend. [8]

The high DALY measure of lower back pain is due, in part, to the difficulty of diagnosis and successful treatment. Non-specific lower back pain, which accounts for 90% of cases, is particularly difficult in these regards. [9] Magnetic Resonance Imaging (MRI) can provide clinicians with a plethora of useful information; however, this information has to be interpreted and can be easily interpreted incorrectly. There are numerous spinal deficiencies that show up in imaging and can lead to a non-specific lower back pain diagnosis, but these deficiencies have also been viewed in individuals who experience little to no pain. [10-13] This indicates that a positive finding on an MRI scan may not necessarily correlate with lower back pain nor point to the true cause of it.

Lower back pain can be classified as either acute or chronic, with the exact criterion of “chronicity” changing depending on the individual clinician, varying from “continuous pain” to “pain for the last 3 months”. [14] Despite not being the primary recommendation for lower back pain, opioids are frequently prescribed as a treatment leading to a quadrupled increase in sales from 1999 to 2010. [15-17] The use of opioids to treat pain unfortunately often leads to addiction and substance abuse, so it is of no surprise that as opioid sales have increased, so too have the rates of abuse and overdose. Unfortunately, it would seem that this problem is progressively getting worse–instances of lower back pain are becoming increasingly common, which means that opioid abuse is as well. [18-19]

As with most problems, preparation and prevention are key–after all, an ounce of prevention is worth a pound of cure. [20-22] Exercise and education combined have the potential to reduce the likelihood of an episode of lower back pain by 45%. [23] Measures such as these are notably easier to implement and manage than dealing with the consequences of entering the recurring cycle of pain. Those who have acute lower back pain–that is, occasional instances of it–are likely to transition to chronic pain if proper care is not sought and administered;
unfortunately, studies have been inconclusive as to the best method to avoid long term pain, due in part to our lack of knowledge on how acute back pain shifts into chronic back pain. [24-26]

2.2 Wearable Sensor Technology for Spinal Monitoring

Developing and monitoring an effective treatment plan for lower back pain is difficult due to a variety of compounding factors, among them a lack of quantitative outcome measurements. Current commonly accepted techniques for gathering quantitative spinal motion data involve in-depth scans, invasive techniques, or extensive amounts of equipment and clinical visits. [27-28] Wearable technologies provide a non-invasive, less expensive way for gathering quantitative spinal motion, and allow for researchers to gather data about spinal motion in daily life, which has heretofore proven to be a large blind spot.

Over the last few decades, wearable and biological sensor technologies have significantly improved in functionality and ease of use, and these improvements have created new possibilities in medicine and biomechanical data collection. Wearable sensors have already become considerably more prevalent in society, with most smartphones having some form of activity tracking, and other more specialized devices being able to track and measure things like heart rate and sleep in addition to activity level. [29] More recently, wearable devices are being used to give measurements of posture and movement in day-to-day life, which has a number of applications including aiding the management of various health conditions. [30-31] With 70% to 85% of the adult population experiencing back pain at some point in their lifetime, wearable sensor technologies with a focus on measuring spinal motion and health are of notable interest. [2]

There are some sensor technologies that are essentially already wearable—most prominently, the smartphone. While the average person does not have their smartphone strapped to their body, it is highly common for people to have their phone on their person for the majority of the day. Smartphones have numerous sensors built into their systems which allow them to perform all of the tasks they have come to be known for; however, these same sensors and features can be harnessed for more scientific means. Smartphones are capable of tracking an individual’s activity data based on the various accelerometers and global positioning software in the device, and this capability by itself has been used to help clinicians collect more objective data about a patient’s recovery and well-being post-operatively. [29] The smartphone is also a good way to establish a line of communication between a more extensive sensor array and the patient, something that multiple systems have taken advantage of. This line of communication is critical to providing real time biofeedback to the individual so the sensor array can be effective in its purpose. [30-32]

Not all sensors are suitable for all purposes, as such there are many different kinds of wearable sensor systems, with more being developed every day. A large portion of these wearable sensor systems make use of inertial measurement units (IMU’s), which combine an accelerometer, a gyroscope, and a magnetometer in order to estimate relative 3-D position and orientation. [33] IMU’s have been tested, validated, and used in numerous studies and the measurements taken from them have been shown to be reliably accurate. [34-35] Due to this
previous work on validating the IMU, they are appealing for use in more esoteric applications, as more attention can be spent on system-level challenges, rather than on sensor development. For example, IMU’s were integrated into a textile device called Lumbatex, which resulted in good usability and comfort for the subjects–by using the IMU as the sensor, the system design could be more carefully thought out and fine-tuned by the research team, which led to those good qualities. [36]

IMU’s are far from the only sensor technology being integrated into wearables; technologies such as surface electromyography sensors, magnets and magnetometers, and strain sensors are also being implemented, with strain sensors being more commonly used than the others. [30, 37-45] Unlike IMU’s, there is a wide variety seen in the strain sensors used in wearable technology–many of the strain sensors were developed in parallel with each other but took very different evolutionary paths depending on what system they were designed for and what metric they were meant to target. Most often the target metric is position or motion data, which is derived from measured strains; this type of relative position and motion measurement is much more heavily based on biomechanics, as frequently the measured strain is dependent on the body type and size of the individual. [41, 44] Some systems seen using strain sensors monitor the change in strain over time, which is particularly useful for motion monitoring. [44]

There are many research groups focused on monitoring and collecting spinal motion data, each with a different overall goal in mind. Motion monitoring is commonly used to assess gait metrics, such as gait cycle, cadence, step length, and number of steps taken; this data can then be used for medical assessment of individuals with various biomechanical disorders like lumbar spinal stenosis. [45] Other teams have taken a focus on providing continuous motion monitoring, which can significantly improve treatment plans, post-surgical recovery, and provide clinicians a more holistic viewpoint of a condition instead of the snapshots that are typically achieved through clinical visits. [37] This continuous motion monitoring has particular use for monitoring lower back-pain related disability, as little is known about how it develops over time and how it affects the motion of daily living. [46-47]

Posture is a huge contributor to spinal health–fittingly, one of the primary uses of wearable sensors in the spine is monitoring posture. Having good posture helps the spine perform its many jobs at optimal capacity, whereas poor posture can lead to back pain and a variety of musculoskeletal disorders. [48] Training people to hold proper posture can be difficult, as it usually requires a trained professional at the very least and can therefore only be done during brief visits. However, this form of training is subject to the Hawthorne effect, whereby people perform the desired task more carefully or exactingly than they would otherwise because they are being observed. This form of training also leaves the individual unobserved and without biofeedback for the majority of their time, making it less effective. [49] With the use of wearable sensors, it is possible to have constant biofeedback for posture training. By having constant biofeedback, individuals can be more quickly and effectively trained in proper posture. [32, 42, 46, 50] The methods by which posture is monitored vary widely; one study presents a means of monitoring posture using a smart necklace, a notebook computer, and a smartphone. This system uses gravitational acceleration and the individual’s skeletal structure identifiers to determine the
posture of the person. The system then notifies the user of incorrect posture, thereby providing the biofeedback necessary for posture training—but this, unlike an instructor, can be used constantly. [20] With the advent of the COVID pandemic, in-person training and treatment methods became highly difficult and undesirable, if not outright impossible. Wearable sensor systems thereby became very useful in providing treatment to patients experiencing low back pain. [46-47]

Currently, many of the success measures for pain treatment and surgical outcomes are subjective, patient-reported-outcome measures (PROMs). These metrics tend to have poor reliability and comparability in addition to being costly to collect. Wearable sensors provide a means of collecting objective data about the patient, thereby improving the ability of clinicians to determine the success of an operation and compare the data with other data sets. [29] One of the first studies to use objective metrics based on patient mobility utilized wearable accelerometers, and the field has only expanded from there. Wearable sensors can provide biofeedback for patients and therapists, thereby increasing the efficacy of physical therapy, which is common after major surgeries and for pain treatment. [29, 39, 51]

### 2.3 The SPINE Sense System

The SPINE Sense System is a portable, inexpensive sensor array used to capture spinal motion in the lumbar spine. [44] The system directly interfaces with a smartphone application through a printed circuit board (PCB) and is comprised of 16 nanocomposite strain gauge sensors that are adhered to kinesiology tape (KT Tape) shown in Figure 2.1. A separate wire piece interfaces with the sensor piece through metal clothing snaps and thereby establishes an electrical connection for the sensors. The wire piece is made of fabric embroidered with the necessary wires, which are then soldered to the snaps. The array is adhered directly to the skin of the lower back and collects skin strain data from the nanocomposite sensors. The array connects to the PCB through the use of a micro-HDMI cord, which is powered by a 9 V battery attached to the array by Velcro. The skin strain data collected can then be used to phenotype motions from a range of individuals, primarily those who suffer from chronic lower back pain and asymptomatic individuals. [52-53]

The alignment and positioning of the sensors on the sensor piece were optimized based on skin strain data obtained using optical motion capture. An array of 48 optical markers were placed on the skin of the lower back of 30 healthy patients who were then recorded performing 17 different spinal motions. A lasso regression technique was used to extract information about where to place the sensors for optimal data collection during the 17 motions performed. [52, 54] The sensors cover the area between the T12 and S2 vertebrae, using the L5 vertebrae as a landmark to align the array with a corresponding mark on the SPINE Sense System. This method has been shown to accurately measure both overall lumbar spinal motion and segmental spinal motion. [52-53]
Eventually, the SPINE Sense System will be used as an alternative diagnostic tool instead of more expensive static imaging options, primarily for people with non-specific lower back pain. An altered version of the SPINE Sense System is currently being used to gather longitudinal data in a study where subjects wear the array for a 48-hour period. The electrical system has the most extensive differences, with the battery cap having an attached buck converter board, allowing for the preservation of power, extending the battery life from 2 hours to 10 hours. During these tests, subjects cannot remove the array, as once removed, the array cannot be replaced. This means the subjects must shower and sleep with it on, which patient reports indicate is not overly comfortable. The KT tape itself is quite stiff, and due to its placement is not comfortable to wear for an extended period of time. Similarly, the SPINE Sense array requires a clinician to apply it to ensure proper alignment as well as due to the difficulty with self-applying anything to the back. The 48-hour study gives more insight to the movement patterns of individuals outside of a clinical setting but is still a relatively small time frame and the nature of the array may impede some otherwise natural motion.

Figure 2.1: The SPINE Sense System with exposed sensors.
3 Design and Prototyping of Z-SPINE System

3.1 Introduction

The current SPINE Sense System has been shown to accurately record lumbar spinal motion data in a clinical setting, which makes it useful as a potential alternative diagnostic tool. This unfortunately leaves a gap in the database—namely, how an individual moves outside of a clinical setting and while unobserved. An altered version of the SPINE Sense System is being used to gather data of this nature in a study where subjects wear the array for a 48-hour period. During these tests, subjects cannot remove the array and thus must sleep and shower with it on, which patient reports indicate is not overly comfortable. The SPINE Sense System requires a clinician to apply it to ensure proper alignment of the sensors as well as the location of the array making self-application difficult. The 48-hour study provides more data about an individual’s lumbar spinal motion while outside a clinical setting but is still a relatively small time frame in comparison to the extent of a person’s lifetime. In order to gather more data about lumbar spinal motion in daily activities over more extended periods of time, a new wearable sensor system needs to be developed.

3.2 Methods

It is intended to utilize the same skin strain sensors present in the SPINE Sense System for the Z-SPINE System. For the Z-SPINE System, the primary constraints and requirements are as follows:

1) Conformity to the motion of the skin.
2) The ability for the garment to be self-applied and removed with minimal difficulty.
3) Comfortability of the design.
4) Reusability of the design.

The most important of these constraints is the skin conformity, followed closely by the self-applicability, hence their numbering designations. Given this, several kinds of pre-existing, form-fitting garment types were investigated, and then selected for further study based on the tightness of their fit. Each garment type was already designed to be self-applicable with comfort in mind—that is, the main thing to be determined was their conformity to the motion of the skin. Among the selected garments were a camisole, a compression shirt, a waist belt, and a pair of high-waisted athletic shorts.

3.2.1 Paint Dot Test Methods

Based upon the hypothesis that skin strain is a good indicator of lumbar spinal biomechanics characteristics, it is critical to determine which type of garment most closely conforms to the motion of the skin over a range of motions, in accordance with design requirement 1. It is assumed that this is best accomplished by the garment that moves the least relative to the skin during a set of movements. The first test used to accomplish this was done by
placing dots of paint on the back of a volunteer from the lab, having the volunteer put the testing garment on top of the paint dots while the paint was still wet, and then perform several functional movements that encompass the kinematic axes of motion present in the human spine. Eight paint dots were placed on the skin of the lower back, between the beltline and the bra line in the pattern shown in Figure 3.1. The size of each dot was measured using a caliper before the testing garment was applied. Once the testing garment was applied, the volunteer performed the following 6 functional movements: maximum extension (bending backwards), maximum flexion (bending forward), lateral bending to the left, lateral bending to the right, rotation to the left, and rotation to the right. Upon completion of the movements, the garment was carefully removed, and the resulting paint smears were measured along their largest axis. These values were then recorded and tabulated for later comparison to evaluate which garments performed the best and would continue to the next iteration of testing. Larger smear patterns indicated poor skin conformity, and smaller ones indicated good skin conformity.

3.2.2 Preliminary Motion Capture Methods

Optical motion capture has long been used as a method of recording human motion, even on the small scale. The level of precision of capture has progressively increased to the point where in the major motion picture Avatar: Way of Water, motion capture was able to accurately record facial expressions, something that was initially thought to be impossible. [56-57] Thus, it was determined that optical motion capture would be used for further assessment of garment skin conformity. As previously discussed, design requirement 1 was deemed the most critical to the overall success of the design, and thus the most in depth tests are dedicated to it. For this assessment, it is assumed that the garment that best accomplishes this has the position data set that most closely matches the position data set of the skin, as determined by relative amplitude error (Eq. 3.1). Conduct the assessment, a volunteer was recruited from the lab (20, F). Eight optical motion capture markers were placed on the volunteer’s lower back, between the beltline and the bra line in the pattern shown in Figure 3.1. This was accomplished through the use of adhesive

Figure 3.1: Pattern and numbering system used in the paint dot test and in preliminary optical motion capture tests.
Velcro patches, as the optical motion capture markers used had Velcro bases. The volunteer then performed the following six different movements which encompass the kinematic axes of motion present in the spine: maximum extension (bending backwards), maximum flexion (bending forward), lateral bending to the left, lateral bending to the right, rotation to the left, and rotation to the right. This procedure was repeated with the optical motion capture markers being placed on the different test garments which were worn by the volunteer, namely the compression shirt, the camisole, and the waist belt.

The x, y, and z position data for each of the optical motion capture markers was obtained for each of the garment types, with the x, y, and z axes being determined by BYU’s optical motion capture lab axes as shown in Figure 3.2. This data was checked over to ensure that it was exported in the proper order so that further analysis could be conducted. The data is divided out by movement and again by marker number (the numbering system used is shown in Figure 3.1) and was used for each garment type and movement. Using MATLAB, the data is plotted on a 3-dimensional grid, with the dimensions in question being the y axis data, the z axis data, and time. This is based on the axis orientation of the optical motion capture lab, wherein the subject stood parallel to the y-axis leading to a minimum of useful information being recorded on the x-axis. This was confirmed in MATLAB processing by varying which axes were plotted against each other. Each marker’s dataset for each movement for each garment is compared to the same marker’s dataset for the skin. Once plotted, the highest and lowest position values are selected for each set of data. These values are then used to calculate a percent error in the amplitudes of the motion of the marker of the garment in comparison to the skin, thereby seeing how well the garment conformed to the motion of the skin.

\[
\text{Relative Amplitude Error} = \frac{|(\text{Amplitude of Skin Motion} - \text{Amplitude of Garment Motion})|}{\text{Amplitude of Skin Motion}} \times 100 \tag{3.1}
\]

This percent error was recorded for each of the markers in each of the motions, averaged, then tabulated. These values were used to determine which of the garments most closely conformed to the skin, allowing for a decision to be made in regard to the best base design. Once the best base design was selected, testing proceeded to try variations of the base design chosen—namely, waist belts with supports, without supports, with supports and silicone patches, and without supports and silicone patches. The silicone patches were placed on the inside of the waist belts so they would be in direct contact with the skin, and underneath where the optical motion capture markers were placed. The base design of the waist belt included four flexible metal “supports” reminiscent of the ribbing found in corsets; for the waist belts with no supports, these were removed with the use of a seam ripper. The methods described previously were then repeated for these four garment types, with the same volunteer performing the movements. Once
the best variation of the base design was determined, all other design elements were incorporated which are detailed in Section 3.6.

3.3 Results

Several garments were chosen from among pre-existing garment types for testing. Each garment chosen is available for public consumption, and thus it is assumed that each one has already undergone a significant design process to ensure that the garments are self-applicable and comfortable, as is general expected of the clothing types chosen. Thus, design requirements 2 and 3 are temporarily disregarded in favor of focusing on design requirement 1—the skin conformity. The skin conformity of the design will heavily impact the quality of data the device is capable of recording, and thus is the most important of the design requirements. Similarly, design requirement 4 is temporarily disregarded, as most clothing items are by nature reusable and any other design features that may impair design requirement 4 are analyzed and developed separately.

3.3.1 Paint Dot Results

The paint dots were measured with a caliper before and after the movements were completed, and they were measured specifically along their longest axis. From visual inspection of each of the pictures taken from before and after, the two paint dots centered along the length of the spine did not change overly much in appearance, and all measurements taken indicated the same. From this, it was concluded that there was a minimum of contact between the garment and the skin along the length of the spine which was largely expected due to the subject’s biomechanics (e.g. the subject’s back has a clear depression along the length of the spine). Each of the three paint dots on either side of the spine showed visual indications of contact between

Figure 3.2: a) A picture of the optical motion capture lab axes, with the z axis coming out of the page and the location of the subject represented by the gray markers, which are placed on the subject’s lower back. b) The plot of one marker’s data for Maximum Extension in the first iteration of testing, with the highest and lowest value of the skin data marked.
the garment and the skin in each of the four tests for the different garment types, usually with the bottom two outer dots showing the largest amounts of smearing.

Of the garments tested, the shirt performed the best, with all dots showing minimal smearing and the largest smear measuring 18.48mm along its largest axis. The camisole also performed well, with all dots excluding the bottom two outer dots showing minimal smearing. The bottom two outer dots had large smear patterns, with the largest measuring 32.18mm along its largest axis. A similar pattern was seen in the waist belt, with the bottom two outer dots having large smear patterns (measured at 47.58mm) but minimal smearing elsewhere. The shorts deviated from this pattern in that there were large smear patterns in all dots (measured at 37.50mm) excluding the ones situated along the spine, which experienced little to no smearing in any of the testing garments. Based on these observations and measurements taken, it was determined to exclude the shorts from any further testing and design iterations.

3.3.2 Preliminary Motion Capture Results

The averaged percent error and standard deviation for each garment for the first iteration of testing in each motion type is recorded in Table 3.1, with the overall average percent error and the overall standard deviation recorded at the bottom for each garment type. It is seen clearly in the table that each of the garment types did notably worse during the rotation tests than in the lateral motion or flexion and extension tests. Studies that have conducted similar motion trials for the spine have also noted less accurate data collection or a higher error in rotational trials. [37-45]

Table 3.1: Tabulated results for the first iteration of preliminary motion capture testing.

<table>
<thead>
<tr>
<th>Movement</th>
<th>Camisole Average Error</th>
<th>Shirt Average Error</th>
<th>Waist Belt Average Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Extension</td>
<td>0.362</td>
<td>0.339</td>
<td>0.080</td>
</tr>
<tr>
<td>Maximum Flexion</td>
<td>0.135</td>
<td>0.175</td>
<td>0.045</td>
</tr>
<tr>
<td>Lateral Left</td>
<td>0.403</td>
<td>0.381</td>
<td>0.303</td>
</tr>
<tr>
<td>Lateral Right</td>
<td>0.165</td>
<td>0.134</td>
<td>0.174</td>
</tr>
<tr>
<td>Rotation Left</td>
<td>0.196</td>
<td>1.069</td>
<td>1.217</td>
</tr>
<tr>
<td>Rotation Right</td>
<td>0.408</td>
<td>1.827</td>
<td>0.654</td>
</tr>
<tr>
<td>Overall Average</td>
<td>0.302</td>
<td>1.448</td>
<td>0.935</td>
</tr>
<tr>
<td>Overall Standard Deviation</td>
<td>0.126</td>
<td>0.666</td>
<td>0.412</td>
</tr>
</tbody>
</table>

The compression shirt had the highest percent error in the majority of the tests conducted, and the highest overall average percent error; these values clearly indicate that the compression shirt is a poor choice for the base design. The waist belt had the lowest percent errors for the lateral and flexion extension movements, whereas the camisole had fairly low rotational percent
errors, to the point where the camisole had the lowest overall average percent error, despite having only one average percent error less than 10%. The low rotational percent errors seen in the camisole may be due in part to data difficulties during those trials, as some of the data sets for the markers got corrupted and returned all zeroes. It could also be due to the four-way stretch material used in the camisole. Whatever the case may be, it was decided to conduct further testing in an effort to combine the success of the waist belt in the lateral and flexion and extension movements with the success of the camisole in the rotational movements. This was accomplished by testing first a waist belt that was made of similar fabric to the camisole and then by testing variants of said waist belt. The averaged percent error for each garment in each motion type is recorded in Table 3.2, with the overall average percent error and overall standard deviation recorded at the bottom for each garment type.

Table 3.2: Tabulated results for the second iteration of preliminary motion capture testing.

<table>
<thead>
<tr>
<th>Movement</th>
<th>Supports Average Error</th>
<th>Silicone and Supports Average Error</th>
<th>No Supports Average Error</th>
<th>Silicone and No Supports Average Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Extension</td>
<td>0.137</td>
<td>0.155</td>
<td>0.270</td>
<td>0.157</td>
</tr>
<tr>
<td>Maximum Flexion</td>
<td>0.149</td>
<td>0.255</td>
<td>0.131</td>
<td>0.140</td>
</tr>
<tr>
<td>Lateral Left</td>
<td>0.264</td>
<td>0.689</td>
<td>0.333</td>
<td>0.188</td>
</tr>
<tr>
<td>Lateral Right</td>
<td>0.080</td>
<td>0.157</td>
<td>0.121</td>
<td>0.096</td>
</tr>
<tr>
<td>Rotation Left</td>
<td>0.224</td>
<td>1.075</td>
<td>0.265</td>
<td>0.200</td>
</tr>
<tr>
<td>Rotation Right</td>
<td>1.530</td>
<td>0.781</td>
<td>0.741</td>
<td>0.475</td>
</tr>
<tr>
<td>Overall Average</td>
<td>0.397</td>
<td>0.518</td>
<td>0.310</td>
<td>0.209</td>
</tr>
<tr>
<td>Overall Standard Deviation</td>
<td>0.558</td>
<td>0.384</td>
<td>0.227</td>
<td>0.135</td>
</tr>
</tbody>
</table>

The waist belt made of a four way stretch material performed notably better in the rotation movements than the original waist belt, indicating that it was likely the kind of fabric used in the camisole that caused the low percent error in the rotational movements. There are a number of different ways in which the skin conformity of the waist belt could potentially be improved—represented by the waist belt variants—and these were tested through the same means as the initial garment selection to determine if they did improve skin conformity. As seen in Table 3.2 above, the variants tested were waist belts with and without supports, and waist belts with and without silicone patches in contact with the skin. There is not a large difference in the performance of the waist belts with and without supports, though the waist belts without supports on average had better skin conformity. There was a notable difference in the skin conformity when silicone patches were added, and the average percent error dropped considerably. The final base design selected was therefore a waist belt made of four way stretch material with silicone patches and no supports, as this combination has the best skin conformity.
3.4 Prototype Iterations

Due to the optical motion capture testing several important design decisions were already made, including the base design and the specific base design variant, these being a waist belt with no supports and the addition of silicone patches underneath the sensor locations. These were important design decisions but were also far from the only necessary ones to make the Z-SPINE System work as intended and meet the necessary specifications. One major design challenge lay in the attachment method for the skin strain sensors and all the requisite wiring and electronics. Also of notable importance is the selection of an easily used closing mechanism for the waist belt base design. Both of these design challenges have a heavy impact on design requirements 2-4; the electronic system needs to be easily used and applied, not impede the comfort of the design, and be in such a configuration as to make the device reusable. The closing mechanism needs to be easily used for the device to be self-applicable, not be overly bulky or stiff as to impede the comfort of the design and be sturdy enough to be used multiple times.

The closing mechanism the waist belt used in the motion capture trials consisted of 14-15 hook and eye closures, with 3 separate rows of the eye half of the closure to allow for adjustment. This mechanism, while very secure, is not easily or quickly used, and thus a simpler closing mechanism was needed in order to more readily satisfy design requirements 2 and 3. Research into other waist belts and similar encircling garments yielded several possible options other than hook and eyes, chief among them being Velcro and zippers. Velcro offers a very simple closing mechanism, both easily understood and used, as well as adjustability in the waist belt to further accommodate different sizes of people. Unfortunately, Velcro also notably impedes the elasticity of the fabric and the motion of the individual wearing the belt due to the stiffness of the Velcro itself and can wear out over time and repeated uses. A zipper, similarly, offers a simple and intuitive closing mechanism that does not overly impede fabric elasticity or subject motion. Unfortunately, due to the tight fit of the design, the zipper alone can be difficult to close properly without aid. Hook and eyes, as previously mentioned, provide a very secure means of closure, but are difficult to use when small and in large numbers. Increasing the size of each of the hook and eye closures and decreasing the number of them improves their ease of use but does not fully close the waist belt. Given these factors, it was determined that a combination of large hook and eyes and a zipper would function the best as a closure mechanism, and best satisfy the design requirements.

As the most important component of the electrical system, significant time was spent determining the best option for the attachment method of the sensors and wiring—best in this case, being determined by how well the option satisfies the design requirements., with the ones of most concern here being requirements 3 and 4—comfort, and reusability. One possibility for sensor and wiring attachment was for the sensors to be glued to the waist belt directly and then the wire piece attached through metal clothing snaps like in the SPINE Sense System; the reverse of this pattern was also considered a possibility. This design would allow for the separation of the wiring and the sensors and be notably similar to the SPINE Sense System allowing for ease in manufacturing; however, it would require 32 metal clothing snaps to fully connect the pieces, increasing the difficulty in using the Z-SPINE System for the average individual. Similarly, having either the wiring or the sensors permanently adhered to the waist belt would complicate
any form of washing procedure, and reduce the design’s reusability. A different design option was the combination of the wiring and sensors into a single piece, which would then be attached to the waist belt. In separating the wiring and the sensors from the waist belt, it allows for the removal of all sensitive equipment from the waist belt. This also allows for a measure of interchangeability in the sensor pieces—in the event that one or more sensors are rendered unusable, it is a simple matter to get a new sensor piece for the waist belt. Any washing procedures also become simplified by the absence of wiring and sensors, as does the overall use of the Z-SPINE System as the number of connection points can be drastically reduced. Unfortunately, the combination of wiring and sensors into one piece complicates the manufacturing process and increases the yield time for each one. It was ultimately decided that the combined wiring and sensor piece would be used.

The manner by which the sensor piece is then attached to the waist belt had several potential variants. Many possible designs attempted to make it so there was only ever one layer of fabric on the individual. Options that attempted to use only one layer of fabric included using a zipper to zip the sensor piece into the waist belt, edges lined in Velcro, and metal clothing snaps. The zipper would have been an easy way to attach the sensor piece while maintaining 1 layer of fabric but encountered significant issues with test implementation as the zipper length needed to match the perimeter of the sensor piece and be sewn into a relatively difficult pattern in the waist belt. Velcro provides good edge alignment and adhesion; however the addition of the Velcro negates the underlying fabric’s elasticity, which would significantly impede the sensor’s ability to accurately record skin strain data. The metal clothing snaps provide a secure way of attaching the sensor piece to the waist belt, and do not interfere with the natural elasticity of the fabric. These clothing snaps also caused stress concentrations in the fabric and provided very poor

![Figure 3.3: a) Photograph of Velcro attachment mechanism tress test. b) Photograph of metal clothing snaps attachment mechanism stretch test. c) Photograph of combined clothing snaps and Velcro attachment mechanism stretch test. d) Photograph of Velcro attachment mechanism prototype.](image-url)
adhesion between the edges of the sensor piece and the waist belt. A combination option of clothing snaps and Velcro was also considered. This option maintained the elasticity inherent in the fabric and provided good adhesion between the edges of the sensor piece and the waist belt, which allows the sensor piece to more closely follow the motion of the skin. The combination of attachment mechanisms also increases the manufacturing yield time. The combination of clothing snaps and Velcro was selected as the attachment method. If the Velcro strips were too large they impeded the fabric’s elasticity—to avoid this, the Velcro was segmented. With the attachment method chosen, it was best for the sensor piece to be on the inside of the waist belt with the sensors themselves facing outward. This orientation leads to the sensors and wires being exposed when there is only one layer of fabric, which is not ideal for the overall robustness of the system, leading to there being two layers of fabric where the sensor piece sits. This design keeps all of the sensors and wiring contained, thereby minimizing the possibility of damage due to exposure.

The electronic components needed to collect the data from the sensors also need to be attached to the Z-SPINE System and consist of a PCB and a power source. The SPINE Sense System makes use of a 9V battery as the power source, and 9V is the voltage requirement for both the SPINE Sense System and the Z-SPINE System. 9V batteries are bulky by the standards of wearable technology, and thus alternatives were sought out so as to improve the comfort of the design. Possible battery alternatives included rechargeable lithium-ion batteries, rechargeable phone batteries, and button batteries inside of a custom battery case. The lithium-ion batteries are rechargeable, small, and lightweight; they also require additional circuitry and can be very volatile to implement. Phone batteries again have the benefit of being rechargeable and are in possession of a thin and flat geometry which is good for the overall comfortability of the Z-SPINE System—however, phone batteries are expensive, and none found had the required voltage. To use button batteries, a minimum of 3 3V batteries had to be linked in series to reach the requisite 9V—traditionally, this would mean they are stacked together but this method would yield a battery just as bulky as a solid 9V one, and so a custom battery pack was designed. The custom

![Image](image-url)
battery pack kept a thin and flat geometry and successfully powered the PCB, though was shown to have a fairly short battery life. Ultimately, it was decided that the 9V battery would remain. Placing the battery on the back as in the SPINE Sense System is inconvenient for the wearer to turn the system on, to replace the battery when needed, and is also quite uncomfortable. As such, the battery position was moved to the lower right side of the waist belt, within easy reach of the individual wearing the Z-SPINE System. The PCB itself remained in the back, centered along the spine and towards the top of the system. This distance between the battery and PCB placement introduced other complications—namely, the connection cable. The distance the connection cable needs to cover will be subject to change and extreme motion, which means the connection cable needs to have a similar degree of flexibility. Wire is not known for its elasticity and at thicker gauges is quite stiff—however, a coil cord is both elastic and flexible, making it an ideal choice for this issue.

3.5 Final Design

Building off of the base design determined in the preliminary motion capture, several features were evaluated and incorporated in order to create a fully functional design that satisfied all design requirements. It was determined early on that the sensors themselves would be separate from the belt as a whole and attached to the belt, much like the current SPINE Sense System. This creates a system that is more readily reusable in the event of sensor failure, thereby helping to satisfy design requirement 4. In order to minimize potential irritants for the wearer and methods of breakage, it was found to be most beneficial to have the sensors and the requisite wire pattern on the same plane of fabric, sandwiched between the belt itself and the silicone patches which are then in direct contact with the skin of the individual. This structure improves the skin conformity of the garment by having silicone in direct contact with the skin, and maintains the comfort of the device, satisfying requirements 1 and 3. The electrical connections between the sensors and the wire pattern are provided by metal clothing snaps that are placed in the sensors themselves, and then soldered to the wires.

![Figure 3.5](image.jpg)

*Figure 3.5: The attachment mechanisms of the sensor piece to the waist belt.*
The sensors are attached to the belt through a mixture of metal clothing snaps and sewn-on Velcro patches. One snap was placed in each corner, and in the center of each side to provide secure attachment points that are not liable to detach during motion. The Velcro was added to bond the edges of the sensor piece more firmly to the waist belt, in order to avoid any form of distortion due to stress concentration around the snaps. In order to maintain the flexibility and elasticity of the fabric, the size of each of the Velcro patches was relatively small, leading there to being segments of Velcro between each of the snaps instead of larger strips. The attachment methods are shown in Figure 3.5.

Pockets for the PCB and the battery are sewn onto the belt, with the PCB pocket being located on the back, in the top center of the belt along the spine and the battery pocket being located on the lower right side for easy accessibility. The PCB pocket has an access port cut into it for the HDMI cord from the sensors and relies on conformity to keep the PCB in place. The battery pocket has an additional fold over flap that attaches with a metal clothing snap to keep the battery in place. The two electrical components are connected by the power cord, which is a highly flexible coil cord, selected because of its ability to stretch with the motion of the individual. All electronic components are removeable, which improves the device’s reusability as this allows for broken components to be replaced, and for the electronics to be safely out of the way during any form of washing procedure.

The front closing method is comprised of two mechanisms: three sets of hook and eye closures, and a zipper. The hook and eye closures are located at the top, bottom, and middle of the belt and act as a way of securely closing the belt and making it easier to zip it up. Each part of the hook and eye closures are attached to elastic bands, which add tension to each set of hook and eyes when closed, making the mechanism more secure. The zipper then holds each edge of the fabric together as a whole. Also at the front is a red alignment indicator, which lines up with the belly button and ensures the proper alignment of the sensors in the back. The closing mechanism used is simple and intuitive, as is the alignment method, both of which allow for the design to be self-applicable, thereby satisfying design requirement 2.
4 Testing and Validation

4.1 Introduction

Back pain affects a huge number of people worldwide—upwards of 80%—with lumbar spinal issues being especially prevalent. [2-3] This condition, affecting people of all ages and genders, significantly disrupts daily life and work productivity. In the United States alone, it incurs substantial costs annually, with most expenses stemming from lost work time and expenses related to diagnosis and treatment. [4-7] Lower back pain ranks high in disability-adjusted-life-years (DALYs), indicating its severe impact on health; a large part of this is due to the difficulty in diagnosis and treatment, especially for non-specific lower back pain, which constitutes the majority of cases. [8-9] Wearable technology has become increasingly more prevalent and is now being used in the medical field for a variety of purposes—the aid in the treatment and diagnosis of chronic lower back pain among them. Of the currently extant wearable sensor technologies, many require clinician supervision to use or are otherwise unsuitable for use over extended periods of time, leaving a significant gap in the data. Development of self-applicable wearable sensor technologies capable of collecting adequate information about biomechanical motion during every-day activities would help to close this gap in the data and significantly impact treatment and diagnostic plans for lumbar spinal conditions like chronic lower back pain.

MRI scans, while informative, can be misinterpreted, as many spinal abnormalities appear in both symptomatic and asymptomatic individuals. [10-13] Lower back pain can be acute or chronic, with opioids often prescribed despite their potential for addiction. Consequently, alongside an increasing number of instances of lower back pain, opioid abuse and overdose are on the rise. [15-19] Prevention through movement and education can significantly reduce the likelihood of lower back pain episodes. [20-22] However, transitioning from acute to chronic pain remains poorly understood, complicating prevention efforts.

Developing an effective lower back pain treatment plan faces challenges, including a lack of quantitative outcome measurements. Traditional methods for gathering spinal motion data are invasive or require extensive equipment and multiple visits. Wearable technologies, on the other hand, offer a non-invasive, cost-effective solution, enabling data collection on spinal motion in daily life, addressing a previous blind spot in the data in addition to helping with pain treatment planning. [27-28] Advancements in wearable sensors, including those in smartphones, have expanded possibilities in healthcare, facilitating activity tracking, heart rate monitoring, and now, posture and movement measurements. With a significant portion of adults experiencing back pain, wearable sensors focusing on spinal health are increasingly valuable. [29-31]

Continuous motion monitoring aids in assessing conditions like lumbar spinal stenosis and improving treatment plans. [37-45] Posture monitoring, crucial for spinal health, also benefits from wearable sensors, offering constant biofeedback for effective training. Wearable sensor
systems have become particularly essential during the COVID-19 pandemic, providing remote treatment options. Unlike subjective patient-reported outcome measures (PROMs), wearable sensors offer objective data, enhancing clinicians’ ability to assess treatment success and customize therapy plans, especially post-surgery or for pain management. [29, 39, 51]

Various wearable sensor systems, like inertial measurement units (IMUs), are being utilized, providing reliable measurements for posture and motion. [34-35] Other technologies, such as electromyography, smartphone applications and biometric tracking, magnetometers, and strain sensors, offer diverse applications. Many of the currently extant wearable sensor devices are limited in the duration of their use and in the methodology of usage, with many requiring clinician assistance or supervision. This allows for snapshots of data to be collected in regard to the individual but provides little in the way of meaningful longitudinal data, nor data about an individual’s unobserved daily activities. There is a need for new, long-term and self-applicable wearable sensor devices to fill this gap in the data and provide additional methods of medical support.

One strain-based wearable sensor device of particular relevance to the current study is the SPINE Sense System, which is a portable and affordable sensor array designed for capturing lumbar spinal motion, with sensor technology based upon high-deflection strain gauges. [44] It connects to a smartphone app via a PCB and comprises 16 nanocomposite strain gauge sensors attached to kinesiology tape. The SPINE Sense System has already proven its utility in differentiating between the motion of healthy individuals and individuals with chronic lower back pain, but the system is not suitable for everyday use. Wearing the array for extended periods can be uncomfortable due to the stiff KT tape and the direct adhesion to the back and requires trained assistance for proper sensor alignment. These restrictions limit the ability of the SPINE Sense System to be used for extended periods of time and preclude it from independent use entirely.

In the current work, we summarize the development of a new, self-applicable and reusable wearable sensor system based upon high-deflection strain gauge technology and evaluated its ability to adequately collect biomechanical information. Since the strain sensors are applied to a removable garment, rather than directly to the skin, they will not accurately follow skin motion, leading to degraded information relative to a skin applied system; but if the proposed approach can still provide key characteristics of biomechanical motion, it could significantly affect out-of-clinic monitoring of lumbar spinal conditions, such as chronic lower back pain. Hence, this study’s purpose was to determine if the new Z-SPINE System provided data of comparable accuracy to skin-adhered devices. Accuracy, in this instance, is defined as the ability of a machine learning algorithm to determine biomechanical characteristics using the data from the Z-SPINE System. The data collected from the new wearable system—called the Z-SPINE System—will be compared to the data collected from the SPINE Sense System, which has already been used to distinguish the motion of chronic lower back pain subjects from that of healthy individuals. [44, 52, 53, 57] The new system will also be assessed for usability; it will be considered to be of usable quality if it attains a System Usability Scale score of 68 or higher.
4.2 Methods

4.2.1 Z-SPINE System Architecture

The Z-SPINE System is comprised of 3 distinct components: the fabric waist belt, the sensor piece, and the electronics. The waist belt is made of a highly elastic four-way stretch fabric. There is a frontal closure mechanism which features three sets of hook and eye closures and a zipper for secure fastening. The elastic bands of the hook and eye sets add tension to the closures when secured. An indicator at the front which aligns with the subject’s belly button ensures proper sensor alignment with the spine, which can be seen in Figure 4.1 b). This simple and intuitive design makes the belt self-applicable. The second primary component of the Z-SPINE System is the sensor piece, which is designed to be detachable from the belt for reusability, ensuring easier replacement if needed. To enhance comfort and durability, both the sensors and the wiring are combined into one piece, which is then sandwiched between the belt and the silicone patches that directly contact the skin, keeping all of the sensors and wiring enclosed—this can be seen in Figure 4.1 c). Metal clothing snaps are used to create the requisite electrical connections between the sensors and the wiring array. The layout of the sensors in relation to the vertebrae of the spine is shown in Figure 4.1 d), and the positions of the sensors have been extensively validated in previous work. [44, 54, 57]

The high-deflection skin strain sensors used in both the SPINE Sense System and the Z-SPINE System were developed and extensively validated in previous work. [44, 52-54, 57-62] These sensors are made using nickel-coated carbon fibers and nickel nanostrands which are uniformly distributed in a silicone matrix. The silicone base allows for the sensors to repeatedly achieve the high strains common of biological material such as the skin. [61] The sensors in question are also piezoresistive, thus when they are deformed their electrical resistance drops significantly, which yields accurate and repeatable measurements of strains ranging from 0% to over 100%.

The sensor piece is secured to the belt with metal clothing snaps and sewn-on Velcro patches—snaps are placed in each corner, and in the center of each side to provide secure attachment points that are not liable to detach during motion. The Velcro is added to bond the edges of the sensor piece more firmly to the waist belt, in order to avoid any form of distortion due to stress concentration around the snaps. In order to maintain the flexibility and elasticity of the fabric, the size of each of the Velcro patches is relatively small, leading there to being segments of Velcro between each of the snaps instead of larger strips. The sensor piece of the Z-SPINE system as well as the attachment method is depicted in Figure 4.1 c).

For the last major component of the Z-SPINE, pockets for the PCB and battery are sewn onto the belt, with the PCB pocket on the back centered along the spine and the battery pocket on the lower right side for easy access. The battery pocket has an additional fold over flap that attaches with a metal clothing snap to keep the battery securely in place. The power cord connecting the PCB and the battery is a flexible coil cord, which allows for stretching during movement. All electronic components are designed to be removeable for washing and replacement, enhancing device reusability.

The Z-SPINE System interfaces with a smartphone application which controls the beginning and ending of data collection periods. As data is collected by the system, it is
transmitted via Bluetooth to the app, and upon completion of a data collection period it is uploaded to a cloud-based database.

4.2.2 Clinical Study Methods

In this study, 30 healthy adults (15 males and 15 females) between the ages of 18 and 65 were recruited. The rationale for excluding participants beyond 65 years of age is the increased risk of significant health complications due to age. Sample size was selected based on a power analysis (G*Power 3.1, ANOVA: Repeated measures, within factors, medium effect size, alpha of 0.05, power of 0.8, 10 measurements per subject) as well as being guided by typical study sizes for similar previously published work. [63] Exclusion criteria for participants in the study included people who experience significant difficulty in basic motion, anyone who has undergone significant orthopedic surgery within the last year, and those whose Body Mass Index is 30 or greater. The demographics of the volunteers, including age, height, and weight, are summarized in Table 4.1. All aspects of the study protocol were approved by Brigham Young University’s Institutional Review Board. Participants provided their written and informed consent prior to participation in the study.

Table 4.1: Participant demographic information, including gender distribution, average height, average weight, and average age.

<table>
<thead>
<tr>
<th>Number of Participants</th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/Female Participants</td>
<td>15/15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participant Information</th>
<th>Average Value ($\pm$ std dev)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>24.3 ($\pm$ 5.8) years</td>
</tr>
<tr>
<td>Height</td>
<td>68.1 ($\pm$ 4.1) inches</td>
</tr>
<tr>
<td>Weight</td>
<td>151.9 ($\pm$ 29.6) pounds</td>
</tr>
</tbody>
</table>

Participants were informed of the details of the study and what would be required of them, including instruction on how each functional movement would be performed. They were then invited to give their consent by reading and signing the consent form. Participant information such as their age, weight, height, and gender was collected in a questionnaire filled out at the end of the data collection. The skin of the participant’s lower back was prepared to have the SPINE Sense System adhered on to it by removing the hair on the back if necessary. The participants had their lumbar spine palpated by an experienced and qualified individual who marked their L5 vertebrae as a landmark to place the SPINE Sense System. The array was then applied to the back with Cramer Tuf-Skin adhesive spray.
Figure 4.1: a) The SPINE Sense System applied to the back of an individual with the accompanying phone application. b) The front of the Z-SPINE applied to an individual. c) The Z-SPINE laid out with the sensor piece in the back exposed. d) A map of the sensor positions of both the SPINE Sense System and the Z-SPINE in relation to the vertebrae of the spine.

Figure 4.2: The kinematic axes of motion present in the spine.
Each participant performed the 14 functional and non-functional movements listed below, with 6 repetitions of each. These particular movements were chosen because they include single-planar motion of the spine in all 3 kinematic planes of motion (shown in Figure 4.2) as well as combinations, multiplanar movements. Resistance data were collected from the SPINE Sense System to capture the motion of the lower back through strain of 16 nanocomposite strain gauge sensors at a rate of 50 Hz per sensor. The 14 movements were as follows: Knee touch, maximum extension, extension fast, extension to the right, extension to the left, rotation to the right, rotation to the left, lateral bending to the right, lateral bending to the left, flexion to the right, flexion to the left, sit to stand, maximum flexion, and flexion fast.

After all the movements were complete, the SPINE Sense System was removed with the help of Mueller Tape and Tuffner remover spray. Following this, the participant was given the Z-SPINE System along with an overview of the system and how to put it on properly. The participant then self-applied the Z-SPINE System, with an experienced and qualified individual double checking after application that it was properly positioned. Following this, the participant performed the 14 movements again, so that the motion data captured from the 16 nanocomposite strain gauge sensors of the SPINE Sense System could be compared to the data captured by the Z-SPINE System. Upon completion of the 14 functional movements, the participant removed the Z-SPINE System, and completed a questionnaire that records the participant’s gender, age, weight, and height. This questionnaire also contained all the questions found in the System Useability Scale, and the methodology for the analysis of the scale is detailed in Section 4.2.3.

The electrical resistance data from the 16 nanocomposite strain gauge sensors for each of the movements performed with both the SPINE Sense System and the Z-SPINE System was obtained for each of the participants and passed through a low-pass filter to reduce the noise in the data, and a Hampel filter to remove any outliers. Figure 4.3 a) shows an example of the resistance curves of 3 sensors during 1 movement, displayed in the same format as the code for data processing uses. Figure 4.3 b) shows the resistance curve of one sensor for two repetitions of one movement. The labeled points in the figure indicate important features that were extracted from the data sets for further processing and analysis.

The SPINE Sense System is directly adhered to the skin of the participant’s back and thus is not transferable to another subject following the test; hence, each subject used a different SPINE Sense System, with associated different calibration values required for each. Thus, all data was normalized to account for this, along with the small variations in placement that occur in the Z-SPINE System. Normalization involved scaling the key resistance parameters extracted from the data relative to the values obtained during the Knee Touch movement at the start of the movement set. This normalization process also helped account for the time-dependent viscoelastic effects of the sensors on the resistance readings of the sensors for the data taken at different times with the same sensor array. [58] Since the Knee Touch data is used for calibration, it is not explicitly used in the model development and error quantification described below; the model uses data from the 13 remaining movements for classification purposes.
The filtering and normalization of each data set is accomplished through the use of Python code. This code is semi-automated, in that it initially selects the key (trough) points needed for further data analysis and presents the initial selection to the user. The user can then accept the automatically selected points, or manually overwrite them if the initial selection was poor. For each of the different movements, only one sensor’s data set has the points selected; the code then applies the time stamp of each selected point to the other sensors’ data sets and collects the data from them. These data are then used to calculate the change in resistance (delta R), the time it takes to perform each movement (T), and the change in resistance divided by the time (Rdot) for each person, each movement, and each sensor. These values, for each sensor, and for each movement, are the attributes (or ‘features’) that are fed into the machine learning model in order

**Figure 4.3:** a) An example of the feature selection code’s initial selection of points and the application of those time stamps to the other sensor’s data. b) The labeled resistance curve for one sensor in one movement for two repetitions. All points selected from the data are used for further processing, with other extracted information that is not labeled being the time spread—being the difference between the maximum and minimum time intervals over six repetitions—and the change in resistance over time, or Rdot.

The filtering and normalization of each data set is accomplished through the use of Python code. This code is semi-automated, in that it initially selects the key (trough) points needed for further data analysis and presents the initial selection to the user. The user can then accept the automatically selected points, or manually overwrite them if the initial selection was poor. For each of the different movements, only one sensor’s data set has the points selected; the code then applies the time stamp of each selected point to the other sensors’ data sets and collects the data from them. These data are then used to calculate the change in resistance (delta R), the time it takes to perform each movement (T), and the change in resistance divided by the time (Rdot) for each person, each movement, and each sensor. These values, for each sensor, and for each movement, are the attributes (or ‘features’) that are fed into the machine learning model in order
to try and predict (or categorize) which movement was associated with each data point. For the tabulated data (i.e., the values of delta R and Rdot for each sensor combined with the interval time, T, and the time spread for each movement and for each subject) to be compatible with machine learning models, any gaps in the data (e.g. due to poor connection for a particular sensor at a given time) needed to be filled with interpolated data or discarded. If more than 40% of any given subject data set was empty, the set was discarded; otherwise, any gaps in the data were filled in with the average sensor value from all subjects for the movement.

In order to test how well the Z-SPINE System can determine biomechanical characteristics, several different machine learning models from the Python library sci-kit learn were utilized to try and predict the movement being undertaken from the extracted data. The machine learning models used were the K Neighbors Classifier, Logistic Regression, Support Vector Machine, and Random Forest Classifier. As part of the 5-fold cross validation test of each model, the models were trained with 80% of the total data set, leaving the remaining 20% to be used to test the accuracy of the resultant models; the data were separated into these two categories such that equal amounts of data relating to each movement were present. The data from the Z-SPINE and the SPINE Sense were kept separate in all regards during this process.

Ideally, the machine learning models would be able to categorize all 13 movements from the test data. However, with only 30 subjects to learn a model from, this is a difficult task for a regression approach that usually learns from large datasets. Hence, models were developed to also try and predict a smaller number of movements or movement categories. One model was developed using the entire dataset and included all of the different movements, for a total of 13 categories. A second model used 7 categories combining the data from similar movements into one encompassing category, thereby using the entire dataset. Flexion max and flexion fast were combined into Flexion, rotation left and rotation right into Rotation, lateral left and lateral right into Lateral, flexion to the right and flexion to the left into Flexion Rotation, extension max and extension fast into Extension, extension to the left and extension to the right into Extension.
Rotation and Sit to Stand was left alone. Data from four movements that are related to significantly different motions were extracted from the dataset for model development; these included flexion max, lateral right, rotation left, and Sit to Stand. Finally, four combined subsets of movements, taken from the 7-category test were used to develop a model; these are flexion, lateral motion, rotation, and Sit to Stand. The different category variations and how they were selected are shown in Figure 4.4. Both the data from the Z-SPINE and the SPINE Sense were subjected to these model variations, with the prediction accuracies of both being compared at the end.

For each category variation, the average prediction accuracy of a 5-fold cross validation test was calculated for 1000 iterations. Confusion Matrices were generated using only 5 iterations of the 5 fold cross validation test, due to limitations with the software used; these were used to visually compare differences between each of the different machine learning models for the Z-SPINE data and the SPINE Sense data.

4.2.3 System Useability Study Methods

A system useability study was conducted which employed the System Useability Scale (SUS)–an industry standard set of scaled statements used to assess the useability of a system that employs a Likert scale to calculate the overall score–to quantitatively assess perceptions of the usability of the design in the context of independent use. [64-66] As a part of the study, the cohort of 30 subjects who participated in the clinical study filled out a questionnaire upon completion of all function movements with both the SPINE Sense System and the Z-SPINE System. This questionnaire recorded the participant’s age, height, weight, and gender, and also contained the System Useability Scale, which participants answered in regard to the Z-SPINE System. Each participant was given an explanation of the system and its features and was allowed to ask any clarifying questions they may have had about the system itself. The questionnaire also contained an optional open-ended question so that participants could express suggestions, comments, concerns, or criticisms of the system. These comments were later reviewed and tabulated. The Likert scale was employed to acquire the quantitative scores each individual gave the Z-SPINE System through the scaled opinion-based questions of the SUS; the average and standard deviation of these scores was then calculated and reported in addition to all open-ended commentary.

4.3 Results

4.3.1 Clinical Study Results

In the process of preparing the processed data sets for use in machine learning models, it was found that the data from the SPINE Sense System required more data cleaning through interpolation (described in Section 4.2.2) than the data from the Z-SPINE System. This is likely due to a mixture of wire disconnects in the SPINE Sense System, leading to a loss of data, and to sensor aging causing the resistances of the sensors to rise to a level that is unusable in data analysis.
For the 5-fold cross validation tests of the various models generated from the data, confusion matrices were output after five iterations. Of the four models used—the K Neighbors Classifier, the Score Vector Machine, the Random Forest Classifier, and Logistic Regression—the Random Forest Classifier consistently performed the best in the 5-iteration tests, hence the results from this model are reported here. The model prediction results for each of the category variations, for both the data from the SPINE Sense and the data from the Z-SPINE are plotted side by side, in addition to reporting a prediction accuracy score in Figures 4.5, 4.6, 4.7, and 4.8.

**Figure 4.5:** a) The confusion matrix for the 4 category test derived from the 13 category data SPINE Sense data, exhibiting a prediction accuracy of 91%. b) The confusion matrix for the 4 category test derived from the 13 category Z-SPINE data, exhibiting a prediction accuracy of 84%.

**Figure 4.6:** a) The confusion matrix for the 4 category test conducted with the 7 category SPINE Sense data, exhibiting a prediction accuracy of 76%. b) The confusion matrix for the 4 category test conducted with the 7 category Z-SPINE data, exhibiting a prediction accuracy of 76%.
The accuracies of the 1000 iteration tests for each of the test variations and for both the SPINE Sense data and the Z-SPINE data is outlined in Table 4.2. For comparison, all four machine model accuracy results are also displayed. As in the 5-iteration tests, the Random Forest Classifier consistently performed well, however it was not always the model that yielded the highest prediction accuracies. The Random Forest Classifier performed the best in all trials involving the Z-SPINE data, and either best or second best in all trials involving the SPINE Sense data. In the SPINE Sense trials, if the Random Forest Classifier was not the best performing model, then Logistic Regression performed the best.
Table 4.2: Prediction accuracy percentages from the 1000 iteration tests for 4 category variation tests and both the SPINE Sense System data and the Z-SPINE System data.

<table>
<thead>
<tr>
<th>Machine Learning Model</th>
<th>SPINE Sense System</th>
<th>Z-SPINE System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 Categories 13</td>
<td>4 Categories 7</td>
</tr>
<tr>
<td></td>
<td>Category Data</td>
<td>Category Data</td>
</tr>
<tr>
<td>K Neighbors</td>
<td>82.12%</td>
<td>79.03%</td>
</tr>
<tr>
<td>VSM</td>
<td>76.75%</td>
<td>64.01%</td>
</tr>
<tr>
<td>Random Forest</td>
<td>82.80%</td>
<td>84.33%</td>
</tr>
<tr>
<td>Logistic Regression</td>
<td>85.95%</td>
<td>83.82%</td>
</tr>
<tr>
<td></td>
<td>58.23%</td>
<td>53.56%</td>
</tr>
<tr>
<td>K Neighbors</td>
<td>62.93%</td>
<td>58.18%</td>
</tr>
<tr>
<td>VSM</td>
<td>71.23%</td>
<td>65.31%</td>
</tr>
<tr>
<td>Random Forest</td>
<td>63.72%</td>
<td>57.15%</td>
</tr>
</tbody>
</table>

As expected, the prediction accuracies progressively dropped as the number of categories increased; this is partially caused by the limitations of machine learning modeling, which requires significant amounts of data for classification of higher numbers of categories. The 4 category variants thereby yielded the highest accuracies, as they had a reasonably sized data-to-category ratio, whereas the 13 category variant performed notably poorly because the model had insufficient data to accurately perceive the differences between all 13 categories, particularly with some of the movements being similar. The accuracies of the machine learning models with the SPINE Sense data are higher than the models with the Z-SPINE data. This is presumably due to the SPINE Sense having sensors adhered almost directly to the skin and being minimally affected by the variability in height and waist measurements present in the cohort of subjects, which affected the fit of the Z-SPINE belt. The direct adhesion to the skin in the SPINE Sense System creates a closer conformity to the motion of the skin, and thereby yields data that more closely reflects the biomechanical motion of the subject.

However, in addition to the raw comparisons of accuracy discussed above, one should also take into account the probabilistic nature of a classification model. If one is trying to select between two states, then there is a 50% chance of selecting the correct state even if the model is no better than random selection. On the other hand, if there are 13 categories, then random selection would result in 7.7% accuracy. Hence, comparing the model accuracy with the performance of a model that uses random selection is another way of quantifying performance. Accuracy values for the best performing models for each case in Table 4.2 were divided by the accuracy that would be obtained by random selection and shown graphically in Figure 4.9. From this perspective, the models for each of the category types perform almost equally well.
A feature analysis was used to determine the most important features (and associated sensors) that the model used in the random forest classification decisions. Shapley values were attained for the cross-validated results, with Shapley values (Shapley Additive exPlanations—SHAP values) being a popular means of determining feature importance based on a game-theory to determine the impact of each feature on the model. \[67\] The results for the model’s categorization of the Sit-to-Stand movement are illustrated in Figure 4.10 for both the SPINE Sense System and the Z-SPINE System, where the most important features are in descending order and the horizontal location of the dots indicated the impact—whether it be positive or negative—that feature has on the model. The colors of the dots indicate whether the variable for that observation was a high value (red) or a low value (blue).

Of the features used in the machine learning, the interval time had the highest and most distinct impact on the model for the Sit to Stand movement. The Delta R and Rdot for each of the sensors did not exhibit large individual impact on the models, with the sensor numbers displayed outside of the feature sum changing with each coding iteration. It should be noted that the sensors located near the lower end of the back had a marginally higher impact than the ones placed higher on the back—the location of each sensor can be seen in Figure 4.1 d). The time spread is never displayed separately from the feature sum, leading to the assumption that is also not a high impact feature.

Figure 4.9: The number of times better than random the prediction accuracies of the best model results displayed in graphical format. The SPINE Sense System results are in blue, while the Z-SPINE results are in red.
4.3.2 Z-SPINE System Useability Study Results

The possible scores of the System Useability Scale are 0-100. A score above 68 is considered above average and represents a device that is intuitive to use. [68] The mean SUS score for this system usability study was 83.4 (“above average”), and the standard deviation of responses was 9.47.

Common positive feedback from the participants included how they felt the waist belt was comfortable and straightforward to use. Many found that the frontal alignment indicator
increased their confidence in the system’s use and found that the hook and eyes in the front aided in putting the Z-SPINE on.

Constructive criticism and concerns largely focused on the fit of the Z-SPINE, particularly in regard to how secure it was during rotational motion. Some individuals indicated that they felt the Z-SPINE lift from their back momentarily or shift position slightly during movements, and expressed concern in how that would impact the device’s ability to accurately track motion. Other common comments included concern or suggestions regarding the positioning and security of the battery, as well as further integration of the electrical and sensor systems into the primary waist belt.

4.4 Discussion

4.4.1 Clinical Study Discussion

The purpose of this study was to determine whether the Z-SPINE System was able to determine key characteristics of human biomechanics that might facilitate studies of chronic lower back pain patients in the future. It was assumed that this should be possible if data collected from the system enabled prediction of movement type with comparable accuracy to a skin-adhered system, the SPINE Sense System, which has already been proven to be capable of differentiating between the motion of a healthy individual and the motion of an individual with chronic lower back pain. Both systems utilized high-deflection strain gauge technology to measure the skin strain of the lower back during motion, making it ideal for comparison purposes. Data was collected from 16 nanocomposite sensors on the SPINE Sense System and on the Z-SPINE System, for 14 functional movements, performed by 30 subjects. The Knee Touch movement was used as a calibration tool and not explicitly included in the model, leaving data from 13 movements to be used by machine learning models to classify the motion types. When a subset of four different motion types were used, accuracy of motion type prediction was 85.95% for the data collected from the SPINE Sense, and 71.23% for the data from the Z-SPINE in the 1000 iteration tests. It is also noted that all category variant tests with both the SPINE Sense data and the Z-SPINE data had prediction accuracies that were at minimum 2.5 times greater than random selection. When the data is viewed in this manner, it is interesting to note that the 13 category variants had higher values than the other category tests, performing at least 3.5 times better than random. While the SPINE Sense System is directly adhered to the skin of the subject, the Z-SPINE System is a technology integrated garment, and thus has no direct adhesion with the skin beyond the fit of the waist belt and the Van der Waals bonds of the silicone that is in contact with the skin. Due to this difference in application, a degradation in the quality of the data was expected; thus stated, it is encouraging to note the achieved accuracy of the models in the present work.

Difficulty with accurately categorizing all 13 movements stems from the low number of data points (30 subjects) for training the models to identify such a high number of categories; furthermore, several of the movements were quite similar in nature. For several pairs of movements, the only differences related to whether the movement was performed at a normal pace or a fast pace, such as for flexion and extension, or the difference related to which side the movement was performed on, as was the case of the other movements excluding sit to stand. The
maximum accuracy reached when trying to predict all 13 movement types was 47.42% for the SPINE Sense data, and 26.97% for the Z-SPINE data in the 1000 iteration tests. Note that for 13 categories, a random assignment of categories would result in 7.7% accuracy; hence, the observed accuracies are much better than random assignment.

The 7 category variant test, therefore combined the movement categories that shared high amounts of similarity in their motion types, which lead to a distinct increase in prediction accuracy—55.01% accuracy with SPINE Sense data, and 38.81% accuracy with Z-SPINE data. Limiting the category number even further by selecting 4 distinct movements—4 from the halved category data, and 4 from the original 13 category dataset—further improved accuracy predictions. It should be noted that higher accuracy predictions were achieved in the 4 category test when the data was pulled from the original 13 category set—not the 7 category data set, despite the 7 category dataset having more data available per category to train the model with. The 4 category test using the 7 category data achieved accuracies of 84.33% with the SPINE Sense data, and 65.31% with the Z-SPINE data, whereas when the 4 category test was conducted using the original dataset the accuracies were 85.95% and 71.23% respectively. Some of the sensors on the two devices used will perceive left and right movements in entirely different ways due to the asymmetry present in those motions—this is presumably the cause of the lower prediction accuracies seen in the 4 category test that was conducted with the 7 category dataset. This is not a substantial increase in prediction accuracy where the SPINE Sense is concerned but represented a notable increase with the Z-SPINE data.

The Random Forest Classifier performed the best of all the models used in most of the category variations. However, in two cases of the trials ran using the SPINE Sense data, the Logistic Regression model performed best. In both cases where Logistic Regression outperformed the Random Forest Classifier, the difference in the reported prediction accuracy was less than 3%. The 1000 iteration tests give a very good idea of the true average percent prediction accuracy as it varies the training and testing groups used for the model 1000 times, ensuring that even if there are combinations that provide excellent training data or combinations that provide terrible training data it does not overtly impact the final prediction accuracy reported.

An example of the resistance data recorded by the same sensor number from the same movement for both the SPINE Sense System and the Z-SPINE is shown in Figure 4.11, which highlights the similarity between the data collected from each system, further indicating the proof of ability for the Z-SPINE. The offset in the two datasets is likely caused by a difference in the pace and timing of movement repetitions by the subject. Likewise, the SHAP value patterns seen in both the SPINE Sense and Z-SPINE are of notable similarity (as demonstrated by the Sit to Stand movement), with the Interval Time having the most impact on the model; the Delta R’s and Rdot’s of each sensor were similarly weighted in terms of impact when compared to each other. The sensors located near the base of the spine had a marginally higher impact than the sensors located farther up the back—this can be seen in Figure 4.10, with the specific SHAP values for some of these sensor features being displayed, and the exact location of each sensor in relation to the spine is shown in Figure 4.11 d).
It is theorized that accuracy predictions could be substantially improved with the addition of more data from a larger cohort of subjects, as this would provide the models with more of the data required for it to differentiate between similar movement types, as well as further train the models with more of the naturally occurring biomechanical variation present between all humans and their unique motion patterns.

The SPINE Sense System that served as a comparison for the Z-SPINE analysis has already been proven to provide valuable biomechanical information regarding chronic lower back pain subjects. An initial study used machine learning, applied to a small cohort of subjects, in order to differentiate between different movement types (similar to this study). In a subsequent larger study, the data from the SPINE Sense System was used to differentiate between the phenotypes of individuals with chronic lower back pain and the phenotypes of healthy individuals. Being able to use technology to make this differentiation can help inform physicians as to the potential success of different treatment plans for chronic lower back pain, thereby improving care for patients and helping to alleviate their suffering.

The outcome from the current study demonstrates that the prediction of biomechanics from the Z-SPINE data is not as accurate as for the SPINE Sense System, due to the difference in application—wearable vs skin-adhered. Since the drop in accuracy is relatively small, it may be possible for the Z-SPINE data to be used to identify chronic lower back pain phenotypes in its current form. Should the accuracy of the Z-SPINE need improvement to achieve this goal, there are two relatively straightforward steps that could increase accuracy to the level of the SPINE Sense System: 1—the collection of a larger pool of data to improve model development of 2—the extraction of more complex features from the data beyond the current features, and related resistance values, for each movement.

It is concluded that the Z-SPINE System has a refined enough ability to distinguish different types of motion based on the machine learning models for a limited number of movement categories. This may provide classifiable biomechanical information about an individual with an ability to distinguish key characteristics of lower back biomechanics relating

\[ \text{Figure 4.11: a) The resistance data of a single sensor on the SPINE Sense System, marked by the initial selection of points of the feature extraction code. b) The resistance data of a single sensor on the Z-SPINE System, marked by the initial selection of points of the feature extraction code.} \]

\[ \text{a) b) } \]
to chronic lower back pain; although some suggested avenues for accuracy improvement have been suggested if the accuracy is not currently adequate. Future work should be done to expand the data set to a larger cohort of subjects, and to include a wider variety of people: in age range, ethnicity, and physical ability. Importantly, the device is designed to track an individual’s motion over extended periods of time and while they are out of the clinic, thus providing a more complete and holistic view of the individual’s state of being, compared with currently available systems (such as the SPINE Sense System).

4.4.2 Z-SPINE System Useability Scale Discussion

The Z-SPINE System received an above average SUS score, at 83.4—this SUS score places the Z-SPINE System into the 93 percentile of all scores in the SUS database. [69] This feedback comes from a cohort of 30 individuals who have all used the system, and thus it is assumed to be valid. It is therefore concluded that the design of the self-applicable vertebral motion tracking system is attractive and usable. It should be noted that due to the process of the study, there is a potential for bias in the responses given by the subjects, as they were first introduced to the SPINE Sense System—which is directly skin-adhered—then to the Z-SPINE instead of being introduced to the Z-SPINE alone.

Much of the positive feedback received from participants about the Z-SPINE was specifically about the ease of use of the system and the comfortability they found while wearing it. These comments in combination with the high SUS score, lead to the conclusion that the system is generally comfortable to wear and intuitive in it’s use. Negative feedback was largely concerned with the fit of the Z-SPINE to each individual and the placement of the battery on the waist belt itself. The battery placement concerns were largely in regard to the security of the battery in it’s sewn pocket, and its placement interfering with flexion motion. Future design iterations may consider placing the battery higher on the waist belt and more directly on the side of the individual rather than more towards the front like it is in the current design. The concerns regarding sizing and minor shifting during motion could both potentially be alleviated by creating more variants of the waist belt size, ensuring a tighter fit for each individual. Future research should consider focusing on a sizing evaluation of the Z-SPINE to create a range of sizes of the system and link those sizes to the waist measurement ranges where they are most effective at gathering accurate biomechanical information.

The future of this device is to be used as a phenotyping tool for people diagnosed with non-specific chronic lower back pain as an alternative to more expensive imaging options like MRIs and X-Rays. These imaging options are also limited in the information they provide, as they only capture data about the spine in a static position, whereas the Z-SPINE System captures dynamic skin strain data which provides valuable information about the segmental motion of the spine. The Z-SPINE System also has the benefit of capturing this data over extended periods of time outside of the clinic, unlike the SPINE Sense System, which—while capable of capturing dynamic skin strain data—is limited to clinical use. The information the Z-SPINE System can capture can help give a better overview of how the patient is moving and what course of treatment would best aid in their recovery.
5 Conclusions and Future Work

During the prototyping process for the development of the Z-SPINE, preliminary motion capture indicated that a waist belt made of a four way stretch material served as the best design base for skin conformity—as it was planned in advance that the Z-SPINE would make use of high-deflection skin strain gauge technology, high skin conformity was highly desirable. The preliminary motion capture also indicated that the presence of silicone patches in direct contact with the skin increased the skin conformity, as did the absence of any form of rigid support in the waist belt.

Thirty subjects each performed 14 different functional movements (one for calibration and 13 for categorization) with both the SPINE Sense System and the Z-SPINE System independent of each other. Classification of the full set of 13 movements, along with subsets of this group, were attempted, using machine learning. Predicting high numbers of categories with a relatively small dataset (30 subjects) is difficult for machine learning models, which operate best with huge quantities of data. The category variants (or subsets) consisted of two 4 category variants, one 7 category variant where similar movements were combined to form one category rather than two, and the full 13 category variant. As the number of categories decreased, the prediction accuracies increased, which indicates that with a larger data set prediction accuracies for the higher category variants could likely be increased.

The models were capable of distinguishing what type of movement was being performed with up to 71.23% accuracy when the number of categories was limited to 4. This is in comparison to the SPINE Sense System, where under the same conditions and utilizing the same models, achieved up to 85.95% accuracy in model prediction. The SPINE Sense System is directly adhered to the skin of the subject whereas the Z-SPINE System is a removable garment, thus the difference between the prediction accuracies was anticipated. The prediction accuracies reported here were achieved by either the random forest classification model or the logistic regression model.

It is concluded that the Z-SPINE System is capable of collecting classifiable biomechanical information, indicating an ability to distinguish key characteristics of lower back biomechanics. Given that the SPINE Sense system has been used to characterize phenotypes of people with chronic lower back pain, it is likely that the Z-SPINE system, with only marginally lower accuracy in the current study, could also be used to study characteristics of motion of people with chronic lower back pain.

Future work should be done to increase the number of subjects tested, providing more data to train the model and increase the accuracy of the models produced from Z-SPINE data. Expanding the variability of the cohort by testing a larger age range, different ethnicity groups, and people of various levels of physical ability or disability should also be emphasized. This would expose the model to a wider range of biomechanical information and improve the robustness of the model in regards to the natural variation that is standard in human motion. Extracting more complex features from the Z-SPINE data to feed into the machine learning models should also significantly improve accuracy and should be explored. Future work might
also focus on achieving a better manufacturing process to improve the consistency of sensor performance across devices to allow for simpler and more reliable data processing.

Work was also done to assess the usability of the Z-SPINE System and both the opinions of individuals regarding the current design, and what design changes may be desired for future iterations. According to the feedback and SUS scores from 30 individuals who all used the system, the Z-SPINE has received an average score of 83.4, which indicates that the system is useable and intuitive to use. Positive user feedback focused on the ease of use of the system and the comfortability of the system, and negative feedback focused on the security of the battery attachment to the belt, battery placement, and the sizing and fit of the waist belt.

Research into the power source indicated that a disposable 9V battery was currently the most economically feasible option, though further research into power sources and power management circuitry could potentially increase battery life and decrease the battery profile, thereby increasing the comfort of the system and address some of the feedback that was given in the system usability study. Power management circuitry in the form of buck converters have already been explored as an option in other studies and were shown to improve battery life from 2 hours to 10 hours, though the circuitry was not implemented in this version of the Z-SPINE System. More experimentation and research could also yield a viable 9V power source that is rechargeable, making the design more environmentally friendly.

In order to address the concerns regarding sizing and minor shifting during motion, future work should consider creating more variants of the waist belt sizes, thereby ensuring a tighter fit for each individual. Future research should further consider focusing on a sizing evaluation of the Z-SPINE to create a range of sizes of the system and link those sizes to the waist measurement ranges where they are most effective at gathering accurate biomechanical information.

Based upon this preliminary study, the Z-SPINE System has the potential to significantly aid the study of biomechanics in the human population. Specifically, it could positively impact the standard of care physicians can provide to patients suffering from chronic lower back pain, thereby helping to alleviate their suffering.
References


61. Wood, D.S., Optimization of a Smart Sensor Wearable Knee Sleeve for Measuring Skin Strain to Determine Joint Biomechanics. 2022


