Exploration of Constant-Force Wristbands for a Wearable Health Device

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Exploration of Constant-Force Wristbands
for a Wearable Health Device

Thomas Alexander Naylor

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

Exploration of Constant-Force Wristbands for a Wearable Health Device

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Wearable Health Devices (WHDs) are an emerging technology that enables continuous monitoring of vital signs during daily life. Issues with constant and consistent data acquisition have been found while WHD technology has developed. The force of the measurement area and movement of the sensors are key mechanical issues that need to be solved for WHDs to become a viable way to continuously monitor health conditions. This work explores Constant-Force Mechanisms (CFMs) as a solution to problems the current WHD industry faces. Additionally, the relationship between force provided from the mechanism, sensor pressure on the wrist, patient comfort, and sensor readings quality are explored and analyzed.

Design requirements for a constant-force wristband were narrowed down to seven critical requirements (mechanism size vs. allowable travel, ability to be used on a curved surface, works well with existing clasps, ease of assembly, direction of travel, material, and force generation). These key requirements need to be considered for a WHD with an integrated CFM to be designed successfully. Two main concepts (buckling beams and tape springs) were prototyped and evaluated against the seven key requirements. The design and testing of a wrist worn sensing band used to gather relationship data among band tension, sensor pressure, patient comfort, and pulsatile signal quality is also presented.

Human subject testing (IRB2020-268) was performed on a wristband with an integrated CFM and the wrist worn sensing band that were developed. The band with an integrated CFM compared pressure on the wrist for both a band with and without an integrated CFM for eight different movement activities. On average the band with the integrated CFM had a lower coefficient of variation for all except one of the activities. The data collected from the wrist worn sensing band shows that tension varies linearly with pressure, and that the pressure vs. tension slope increases with increasing wrist width. There also exists a linear relationship between tension and patient pain/comfort, but pressure does not show an effect on the patient discomfort or pain experienced. Signal quality when measured in the range of of 0-4 N and 0-20 kPa does not have a direct correlation to either tension or pressure.

Keywords: compliant mechanisms, constant-force mechanisms, wearable health devices
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CHAPTER 1. INTRODUCTION

Perhaps the most prevalent long-term illness among people in the United States is diabetes. Estimates from 2015 suggest that there are over 30 million people in the United States, or 9.4% of the population, with diabetes [7]. One of the difficulties in treating diabetes is monitoring blood glucose levels. Current practices tend to involve either pricking one’s finger for blood up to 10 times per day or leaving a small needle embedded in the skin to continuously monitor blood glucose levels. So far, there have been no successful products that are continuous noninvasive glucose monitors. There have been a few products and research products that have noninvasively (without having to draw blood or insert anything into the skin) monitored blood glucose levels. These, however, have not been able to noninvasively and continuously monitor blood glucose levels without needing frequent calibration and being uncomfortable for the user. Brigham Young University is conducting research to create a device that would use two sensors, an optical spectrometer and bio-impedance electrodes, to gather biological signals, correlate them, and predict glucose levels. For this device to be successful the sensors need to collect accurate data continuously. Two problems associated with this are the movement that a wrist worn device will experience and the swelling and shrinking a wrist undergo during the day. Therefore, developing a wristband that will be able to keep the sensors in position is a crucial part of the device. The wristband must also be comfortable enough and attractive enough that the user will want to keep wearing the device. Methods to develop a band that can meet these requirements need to be understood better.

1.1 Background

Long term illness is one of the most difficult medical problems for doctors, physicians, and patients to deal with. The lack of information about a patient’s vitals throughout the days and weeks between physician visits makes it difficult to measure the effect different treatments have on a patient. Having essentially continuous data will help physicians better combat the diseases peo-
ple face and will enable individuals to make better choices in day to day living. Wearable Health Devices (WHDs) are an emerging technology that enables continuous monitoring of vital signs during daily life, while minimizing discomfort and interference with normal activities [8]. According to Statista [9] the worldwide revenue of the wearable devices market is currently around $34 Billion and projected to be around $44 Billion in 2020. WHDs are a way to combat the difficulties that arise in the monitoring of long term illnesses.

However, WHDs are not without difficulties of their own; a paper published in the Dove Press journal: Medical Devices: Evidence and Research [10] that discusses advances in continuous blood glucose monitoring devices concluded that that “none of these technologies have produced a commercially available, clinically reliable device; therefore, much work remains to be done.” One of the main problems WHDs experience is the calibration of sensors; the force of the measurement area and movement of the sensors are key issues that need to be solved for WHDs to become a viable way to continuously monitor health conditions. Applying a constant force to the measurement area can solve these problems. One way to apply a constant force on the sensors may be through an integrated Constant Force Mechanism (CFM).

1.1.1 Constant-Force Mechanisms

![Realistic Force - Deflection curve of a constant force mechanism.](image)

Figure 1.1: Realistic Force - Deflection curve of a constant force mechanism. [1].
A CFM is used to maintain a constant output reaction force throughout a large range of motion (see figure 1.1). Hence, CFMs are widely used in overload protection, biomedical applications, and robot end-effectors. [11] Wang and Xu present a survey of state-of-the-art design and modeling approaches for CFMs that classifies the mechanisms into five kinds of conventional rigid-link constant-force mechanisms (curved surface, double slider, hinged lever, oblique springs, C-shape spring) and five kinds of fully compliant constant-force mechanisms (stiffness combine, curved-beam, shape optimized, cross-spring, constant-force compression mechanism).

The design and modeling of these ten types of constant-force mechanisms are fully explored by Wang and Xu. The different pros and cons that each of five conventional rigid-link constant-force mechanisms and five compliant constant-force mechanisms will be summarized below. See Figure 1.2 for an example of each compliant constant-force mechanism type.

- **Curved surface constant-force mechanism**
  - Pros: Large constant-force stroke, compact structure, good loading distribution, simple mathematical model
  - Cons: Low output accuracy, difficulty in machining, triangular notch in working surface

- **Double slider constant-force mechanism**
  - Pros: Simple structure, simple machining technology, high interchangeability, simple mathematical model
  - Cons: Large output error, suffers from friction, wear, and backlash

- **Hinged lever constant-force mechanism**
  - Pros: Simple mathematical model, easy to be realized, high interchangeability, simple structure
  - Cons: Low output accuracy, large size

- **Oblique springs constant-force mechanism**
  - Pros: Easy to be realized, simple structure
  - Cons: Large output error
• C-shape spring constant-force mechanism
  – Pros: Easy to be realized, simple structure, compact size, large constant-force stroke
  – Cons: Large output error

• Shape optimized constant-force mechanism (Figure 1.2a)
  – Pros: Compact size
  – Cons: Suffers from natural defects of conventional technologies, low output accuracy, complex design and optimization process

• Curved-beam constant-force mechanism (Figure 1.2b)
  – Pros: Compact size, large constant-force stroke, high output accuracy, reduced driving force
  – Cons: Requires large manufacturing precision, sensitive to parameters, complicated mathematical model, complex design and optimization process

• Stiffness combine constant-force mechanism (Figure 1.2c)
  – Pros: No wear, backlash, or friction, high output accuracy, simple structure, low cost, low requirement for material, reduced driving force
  – Cons: Requires large manufacturing precision, sensitive to parameters, complicated mathematical model, small constant-force stroke

• Constant-force compression mechanism (Figure 1.2d)
  – Pros: Constant compressive force output, simple structure
  – Cons: The output force is not perfectly constant

• Cross-spring constant-force mechanism (Figure 1.2e)
  – Pros: Constant torque output
  – Cons: Potential residual stress from manufacturing,

1.1.2 Wrist Information

Developing a wrist worn health monitoring device requires an understanding of certain wrist properties such as cross sectional shape of the wrist, location of the radial artery, user preferred location of wrist worn devices (closer to vs. further from the hand), wrist circumference, wrist width (breadth), wrist height, and wrist ratio (R = wrist height/wrist width).

Multiple studies have been performed that provide a vast amount of information on average wrist sizes for both males and females [12–20].

The wristband must be able to accommodate the significant wrist circumference distribution among the target population along with the associated arc length distance from the top of the wrist to the radial artery (we will refer to this as the top-to-radial distance). There are no published
anthropometric studies that directly report the top-to-radial distance but there are several that report wrist circumference and wrist ratio/index (wrist height divided by wrist width). We have found that a combination of these two measurements along with an educated guess on the location of the radial artery on the wrist cross section gives a reasonably accurate estimation for the top-to-radial distance. Based on observation and comments from published sources, we have modeled the wrist cross section as an oval. No anthropometric studies we have found report any correlation between wrist circumference and wrist ratio, meaning it may be possible for two people with the same wrist circumference to have very different wrist ratios and therefore different top-to-radial distances. Figure 1.3 below shows the top-to-radial distance could possibly range from 40 mm to 72 mm.

![Figure 1.3](image)

Figure 1.3: A possible range for the top-to-radial distance based on anthropometric measurements. To make this plot, the wrist circumference was varied from 136 mm to 219 mm and the wrist ratio was varied from 0.56 to 0.86 in 0.02 increments.

1.1.3 Wearable Health Devices

Wearable health devices cover a wide range of products. Some examples are waist worn devices [21–23], shirt and vest type devices [24, 25], hand worn (glove and ring style) [26, 27], and wrist worn devices [28–31]. These devices are designed to measure a wide range of biometric data such as glucose levels [10, 32, 33], blood pressure [29, 34], blood oxygen saturation and pulse data [35].
1.2 Research Objectives

The objective of this research is to design a wearable wristband that allows a constant contact pressure to be used in the application of a wearable medical device. Knowledge of CFMs and their ability to produce a constant force over a large displacement will be leveraged in the design of the wearable band. This project will also seek to apply compliant mechanism theory to design and test a constant-force wristband. Additionally, the relationship between force provided from the mechanism, sensor pressure on the wrist, patient comfort, and sensor readings quality will be explored and analyzed. There is currently a lack of data in the field that relates to optimal pressure for wearable medical devices, and this research will provide a resource to help future WHD designers understand benefits and drawback with varying wrist pressure. Chapter 2 will focus on design principles for constant-force wristbands as they apply to wearable health devices. Chapter 3 focuses on developing the relationships among band tension, sensor pressure, patient comfort, and pulsatile signal quality for wrist worn health monitoring devices. Chapters 2 and 3 are technical papers that have been submitted to the ASME Journal of Mechanical Design (JMD) and the ASME Journal of Medical Devices respectively.
CHAPTER 2. DESIGN OF CONSTANT-FORCE WRISTBANDS FOR A WEARABLE HEALTH DEVICE

This chapter presents the design and testing of a Wearable Health Device (WHD) with an integrated Constant-Force Mechanism (CFM). An integrated CFM can keep pressure on the wrist constant or near-constant, thereby solving one of the main difficulties (movement of and varying force on the sensor area) that WHDs face. The design requirements for a constant-force wristband were narrowed down to seven critical requirements. Multiple CFMs were explored with two main concepts (buckling beams and tape springs) prototyped and evaluated against the key requirements. The tape spring concept was chosen for human subject trials testing due to the mechanisms better performance compared to the buckling beams concept. The human subject testing (IRB2020-268) compares pressure on the wrist for both a band with and without an integrated CFM for eight different movement activities. On average the band with the integrated CFM had a lower coefficient of variation for all except one of the activities.

2.1 Introduction

Wearable Health Devices (WHDs) are an emerging technology that enables continuous monitoring of vital signs during daily life, while minimizing discomfort and interference with normal activities [8]. WHDs are a way to combat the difficulties that arise in the monitoring of long term illnesses. However, WHDs are not without difficulties of their own; a paper by So and Choi [10] that discusses advances in continuous blood glucose monitoring devices concluded that that “none of these technologies have produced a commercially available, clinically reliable device; therefore, much work remains to be done.” One of the main problems WHDs experience is the calibration of sensors [10]. Several other challenges (Multi-Modality/Multi-Functionality, Electrode Dc Offset, and Motion Artifacts) are described by Kim et al. [36]. The force of the measurement area and movement of the sensors are key mechanical issues that need to be solved for WHDs to
become a viable way to continuously monitor health conditions. Work done by Taji et al. demonstrates that pressure of the sensing area has an effect on skin-impedance in wearable biomedical measurement devices [37]. Applying a constant pressure to the measurement area can help solve these problems. One way to apply a constant force on the sensors may be through an integrated Constant Force Mechanism (CFM).

A CFM is used to maintain a constant output reaction force throughout a large range of motion (see Figure 2.1). Hence, CFMs are widely used in overload protection, biomedical applications, and robot end-effectors [11]. Research done by Weight and Mattson [38] demonstrates the usefulness of CFMs in electronic connector design, where maintaining contact is extremely important.

Regardless of the specific purpose of the WHD, integrating a CFM can help to improve the functionality of the device by reducing movement of the device while maintaining user comfort. This chapter focuses on developing critical design requirements to help in the design of constant-force wristbands. Development, fabrication, and testing of such a band are described to provide an example of a WHD with an integrated CFM.

2.2 Background

Long term illness is one of the most difficult medical problems for doctors, physicians, and patients to deal with. The lack of information about a patient’s vitals throughout the days and weeks between physician visits makes it difficult to measure the effect different treatments have on a patient. Having essentially continuous data will help physicians better combat the diseases people face, and will enable individuals to make better choices in day to day living.

2.2.1 Existing Health/Fitness Bands

There are many health/fitness smart watches in existence. These bands all use conventional band and clasp combinations. Apple recently patented a new method for enhanced photoplethysmography (PPG) sensor signal collection [39]; existing bands use optical photo sensors in concert with LEDs that generate a PPG signal. Wallen [40] tested four wrist-worn devices (Apple Watch, Fitbit Charge HR, Samsung Gear S and Mio Alpha) to determine the accuracy of the heart rate and
energy expenditure. They found that device estimates of heart rate via photoplethysmography were within 1–9% of reference estimates and concluded that the four devices were accurate in measuring heart rate. These devices may be able to measure heart rate; however, the force of the measurement area and movement of the sensors are still issues that need to be solved for WHDs to become a viable way to continuously monitor health conditions without needing frequent calibration and being uncomfortable or inconvenient for the user. It is important to note that other methods of sensing biometric data are considered in the scope of WHDs. These include tactile sensors [30], electrocardiograms (ECG), electroencephalograms (EEG), electrooculograms (EOG), and electromyograms (EMG) [41].

2.2.2 Constant-Force Mechanism Categorization

Currently CFMs are used in a variety of ways including electrical connectors [38], force regulation and overload protection [42], microgrippers [43], and a precision positioning stage [44]. However, there is a lack of work that integrates CFMs to create a constant-force wristband. Figure 2.1 shows an example of a force vs. displacement curve of a constant-force mechanism.

Wang and Xu [11] present a survey of state-of-the-art design and modeling approaches for CFMs that classifies the mechanisms into five kinds of conventional rigid-link constant-force mechanisms (curved surface, double slider, hinged lever, oblique springs, C-shape spring) and five kinds of fully compliant constant-force mechanisms (stiffness combine, curved-beam, shape optimized, cross-spring, constant-force compression mechanism).

2.3 Design Requirements

As with any design there are key requirements that need to be met in order for the design to be successful. The requirements for a constant-force wristband were narrowed down to seven critical requirements that are listed below.

- Mechanism size vs. allowable travel - A majority of CFMs have an exponential relationship between size of the mechanism and the amount of travel that the mechanism provides. The wristband design must consider the distance the band needs to be able to expand or contract.
Many mechanisms may be excluded due to this relationship. Size constraints can help narrow down the type of mechanism that should be used.

- Ability to be used on a curved surface - A band that is designed to be worn on the wrist needs to consider that wrists come in a wide range of curvatures and sizes. The placement of the mechanism determines the amount of curvature that the mechanism will need to be able to handle.

- Works well with existing clasps - There are a handful of different methods to secure the wristband. Some mechanisms perform better with certain clasp types. If the style of clasp is a major concern some mechanisms may be disqualified.

- Ease of assembly - The assembly of the band and complexity of the mechanism need to be considered when choosing a CFM.

- Direction of travel - The desired direction of the force generated is important. The wristband may operate using compression or tension as the driving mode of movement. Most mechanisms can be designed in a way that allows travel in either tension or compression. However, this can added unnecessary complexity to the wristband design.
• Material - The material requirement includes design considerations such as fatigue life, material creep, corrosion resistance, and if it needs to be hypoallergenic. Other material considerations include sensorial properties, and intangible characteristics discussed by Karana [45].

• Force generation - The force required for the device to work properly while maintaining user comfort is critical when designing a band that will be worn to generate a constant pressure on the wrist.

These critical requirements form the foundation for the development of constant-force wristbands. Each designer may prioritize different requirements but all are important to consider for the design.

2.4 Chosen Concepts

Different constant-force mechanisms were explored to find a mechanism that could be integrated into a wristband. Two main mechanisms, buckling beams and tape springs, were chosen to further explore and prototype. The buckling beams mechanism falls into the constant-force compression mechanism category and was chosen because of the simplicity of the structure. Other mechanisms were considered such as combination stiffness and curved-beam constant-force mechanisms; however, they were deemed to be similar enough to the buckling beams mechanism that only one needed to be further developed for proof of concept.

2.4.1 Buckling Beams Mechanism

This concept is based on the fact that beams in buckling will produce a near constant force vs displacement curve (see Figure 2.2) for a certain range of motion. Note that the Figure is for a single beam, where our mechanism has two buckled beams. The mathematical model developed by Jensen and Holst [46] served as the starting point for evaluating the buckling beams concept. This model is based upon elliptic integral solutions for a buckled beam. The model showed that the desired travel was achievable in the size range desired. Beams can be made from many different materials and a wide range of sizes. Three main materials, TPU, NinjaFlex and spring steel, were considered in the initial prototype stage of the design. TPU and NinjaFlex were used
Figure 2.2: A Force vs Displacement curve for a buckled beam with dimensions of .1 mm in-plane thickness, 20 mm - beam length, .5 mm - out-of-plane width, and 200 GPa - Young’s Modulus in buckling for the ease and speed of prototyping. Multiple prototypes were created for proof of concept and concept evaluation. The first prototype (shown in Figure 2.3) was 3D printed to test the mechanism and range of motion obtained only. The next prototype was a full 3D printed NinjaFlex band with the mechanism in line. On this prototype a rigid stabilizing bridge was added to the housing.

2.4.2 Tape Spring Mechanism

Tape springs are commonly used in constant force and constant torque applications (such as a tape measure). Tape springs are created from pre-stressed metal, typically stainless steel, that is coiled around itself. The end of the spring is pulled, uncoiling the spring which in turn resists the force. While the spring uncoils, the radius and curvature of the portion over the drum remains virtually constant. This is what provides the constant force. The spring must be extended 1.25 times the diameter of the coiled spring before it reaches a relatively constant force. The tape springs in each prototype that was developed used a watch pin and a 3D printed drum to hold the spring as the band was pulled (see Figure 2.4). Three different methods were used to attach the spring to
the wristband (see Figure 2.5). The first method was to attach the ends together with a small wire that was twisted through corresponding holes in the spring and the band. The next method used a rivet to connect the band and spring. The final method is called a scalloped connection; Figure 2.5c shows the shape of this end condition. The scalloped end slides through a slit in the band and then twists to maintain the connection. The prototypes that were made for the tape spring band only varied with the attachment method and clasp type.
2.5 Evaluating Concepts

Each of the chosen concepts was evaluated using the key requirements described previously. This section describes how the mechanisms were evaluated and their performance for each key requirement. This section is laid out with each requirement explained in the first paragraph with the paragraph numbered (1) referring to the buckling beams concept and paragraph numbered (2) referring to the tape spring concept.

2.5.1 Mechanism size vs. allowable travel

The maximum size that the mechanism could occupy was a constraint that was considered at the start of the wristband development. The width and depth of the mechanism were the most important size restrictions with the maximum width being 30 mm and the depth being 10 mm. Length was less of a concern for the mechanism as long as there was room for the clasp and other electronics, approximately 60 mm. There were two main reasons behind the size constraints. First,
the band needed to be aesthetically pleasing which meant that it could not be extremely bulky. Second, the mechanism could not take up the space that would be needed for the electronics and other band components like a face and clasp. The amount of travel desired from the mechanism was a minimum of 5 mm at the very least.

1. The maximum width and depth constraints were used to maximize the amount of travel possible with the concept. Figure 2.3 shows the 3D printed prototype mechanism at rest and in the fully extended position; 5.5 mm of travel was obtained. The TPU prototype was on the extreme size of the mechanism. The beam model using spring steel used beams that were .1 mm by .5 mm by 20 mm (in-plane thickness by out-of-plane width by beam length) compared to the TPU beams that were 1 mm by 10 mm by 20 mm for the same amount of travel and force generated. The mechanism used two buckling beams to keep balance and to generate the required force. The dimensions for the complete mechanism are 30 mm by 10 mm by 50 mm (width by depth by length).

2. The tape spring mechanism allows a large amount of travel for a relatively small volumetric size. The tape spring used in the mechanism is 9.525 mm (.375 in) wide with an outer diameter of 3.708 mm (.146 in); this tape spring provides up to 76.2 mm (3 in) of travel. Figure 2.6 shows the required components to house the tape spring and the attachment to the wristband. The final dimensions of the tape spring prototype were 20 mm by 7 mm by 30 mm (width by depth by length).

2.5.2 Ability to be used on a curved surface

It was originally considered that there would be sections of the wrist would be flat enough for planar mechanisms to function. As mechanisms were prototyped it was realized that any part of the wrist had enough curvature that introduced out of plane forces that were significant enough to cause poor performance from those mechanisms.

1. There are two main problems the buckling beams concept faces in regards to this requirement. First, as shown in Figure 2.7 we see that if the beams are not restrained the mechanism
fails. Second, when the mechanism is put into a housing to limit the degrees of freedom the system experiences a high amount of friction which reduces the effectiveness of the mechanism. One solution was developed. However, it restricts the placement of the mechanism on the wristband to either the top or bottom of the wrist on the “flat”. This solution is connected to the type of clasp used in the band and is discussed more in the clasp requirement section.

2. Depending on the type of band used (Velcro, leather, plastic) and the attachment method (wired, riveted, scalloped end) some friction between the end of the tape spring and the
housing was experienced. There were no other problems caused by the mechanism being curved around the wrist.

2.5.3 Works well with existing clasps

One of the desires was to have the user be familiar with the band so that the use was intuitive. A way to accomplish this was to limit the design to clasps that are currently on the market. The common clasp types that were explored consist of buckle, Velcro, tri-fold, button, and magnetic clasps.

1. With the limit of the mechanism being placed either on the top or bottom of the wrist, not all of the aforementioned clasps are viable. The mechanism was integrated into the tri-fold clasp and a proof of concept using a linear spring was prototyped (see Figure 2.8). Other clasps could potentially be used if the mechanism was integrated on the top of the wrist behind the watch face but they were not explored further during this project.

2. The tape spring mechanism was able to successfully integrate with all of the clasps that were tested into wearable prototype bands with the tape spring mechanism. These four clasps were
Figure 2.8: Tri-fold clasp with integrated spring

Figure 2.9: Tape spring band example with a buckle clasp and an example of a Velcro clasp

Velcro, buckle, and two types of tri-fold clasps (the traditional tri-fold and a tri-fold button combination). Figure 2.9 shows two examples of the bands with different clasps.
2.5.4 Ease of assembly

Ease of assembly comes down to how many parts are included in the mechanism and the complexity of how the parts fit together. There are no numerical values for part count or assembly time set, but they must be considered to make sure that the chosen concept is the best suited for the problem being solved. Work by Boothroyd and Dewhurst included multiple quantifiable metrics to use when designing for manufacturing and assembly [47]. For our specific analysis a qualitative approach was used to judge ease of assembly.

1. The number of parts and manufacturing process is dependent on the placement of the mechanism. If the mechanism is going to be inline with the band it would be one piece of spring steel cut and bent then overmolded into the band itself. If the mechanism is being housed in the tri-fold clasp there are five parts in total that would need to be assembled in order.

2. The tape spring mechanism consists of the tape spring, a central drum, the spring cover, and a pin to attach the components. The main difficulty comes from the assembly of the parts; this was lessened when the scalloped end condition was added to the tape spring. The mechanism needs to be attached to the band and then fed into the spring cover from the back which is then attached to the watch face with a watch pin.

2.5.5 Direction of travel

For the band to work the mechanism used needs to generate force when pulled on. As the band is being put on the mechanism needs to engage and tighten after the clasp is connected. Many CFMs are designed to work in compression only and need to be arranged differently or modified to work in tension.

1. The buckling beams and other associated mechanisms are all designed for compression situations. For these mechanisms to work in tension a unique configuration was developed. This allows the buckling beams mechanism to work in tension in line with the band as seen in Figure 2.3.
2. Tape springs meet this requirement well without any extra work required. They work in tension and can be tested simply.

2.5.6 Material

Material is a key component in design, especially with devices that are being developed for health and wellness market. All of the materials used in the mechanism need to be hypoallergenic. Another concern with material is it needs to be durable enough for a wearable health device that will be used for the majority of the day each day.

1. The buckling beams mechanism was originally tested using TPU and Ninjaflex 3D printing materials. During those tests the prototypes experienced material creep after a short amount of time in their deformed states. It was concluded that the beams would need to be made from spring steel to prevent creep and allow for the strain the beams would experience.

2. The materials used in the tape spring mechanism other than the tape spring itself, which is spring steel, can be made from a variety of materials including hypoallergenic metals or plastics. The prototype mechanism has seen slight deformation in the tape spring due to the attachment method to the band, but a new end type (scalloped) has been manufactured to solve this problem.

2.5.7 Force generation

To determine the desired force of the mechanism in the band a simple mathematical model for the wrist and band was created (see Figure 2.10). A few generalizations were made to simplify the wristband model when finding the pressure \( P \). The wrist was approximated as a circle with a diameter \( D \). The wrist is not a circle but this provides an acceptable estimate for pressure. The tension \( T \), in the wristband was assumed to be constant through the band. Starting with the equation:

\[
P = \frac{F}{A}
\]  

(2.1)
where the force $F$ is twice the tension in the band and the area is the diameter of the wrist $D$ and the width, $w$, of the band. The equation becomes:

$$P = \frac{2T}{Dw}$$

(2.2)

Using data from Garrett [14], [13], [15], Gordon [17], [16], Moghtaderi [20], and Noudeh [18] for wrist circumference and Moghtaderi [20] and Boz [12] for wrist ratio (height to width) a mean wrist diameter was calculated. The ratio $R$ of wrist height $a$ and wrist width $b$:

$$R = \frac{a}{b}$$

(2.3)

and the equation for circumference $C$ of an oval:

$$C = 2\pi \sqrt{\frac{a^2 + b^2}{2}}$$

(2.4)

were used to calculate an effective diameter $2b$ to be used in equation (2).

$$D = 2b = 2\sqrt{\frac{2 + \frac{c^2}{4\pi^2}}{R^2 + 1}}$$

(2.5)

The minimum and maximum wrist circumference was 135.88 mm and 219.09 mm respectively. The minimum and maximum wrist ratio was .563 and .86 respectively. Using these values the mean wrist diameter was calculated at 65.1 mm with an absolute minimum of 46.38 mm and an absolute maximum of 85.94 mm.

We started with the diastolic blood pressure and took about half of that value for our desired pressure around 4 kPa. The band needed to stay snug but not cut off blood flow. The ideal pressure is an area where further development is needed. The pressure that was prototyped was around 4 kPa. This corresponds to a mechanism force of around 3 N or .674 lb. The springs that have been used in the prototype bands developed have a force of .64 lb (2.847 N) which has resulted in a snug but comfortable fit. The pressure from the prototyped spring ranges from 2.6 kPa to 4.9 kPa with the mean diameter resulting in a pressure of 3.5 kPa. A width of 25 mm was used in the above calculations.
Figure 2.10: Model for pressure generated on the wrist from the wristband

1. The force generated in the buckling beams mechanism can be changed by modifying the geometric properties of the beams. The prototype with beams .1 mm by .5 mm by 20 mm generates 2 - 3 N through their full travel. The force is not as constant as other mechanisms, but it is within the desired range for the wristband.

2. The tape spring mechanism force can be tuned through the width of the tape spring without changing the diameter which is important to keep small to reduce the bulkiness of the overall mechanism. The current prototype’s force displacement curve is shown in Figure 2.11.

2.6 Experimental Procedure

An experiment (IRB2020-268) was developed to further test the effectiveness of the integrated CFM. The tape spring was chosen as the mechanism in the experiment because it outperformed the buckling beams mechanism in the analysis conducted.

In this experiment, the consistency of pressure provided from a constant-force wrist band was measured. The wristband must maintain a constant pressure where the sensors are placed during everyday activities to be useful in the desired application; because of this we measured pressure provided from a constant-force mechanism during activities a person might perform in
Figure 2.11: Force-Displacement curve for the tape spring mechanism used in testing. Data was taken on an Instron tensile test machine.

their normal daily routine. The pressure sensor was located over the participants’ radial artery to simulate a sensor package in that area. Tests with and without the spring housing were performed for comparison. The band without the spring housing instead had a fixed length of band that was added. Both bands used a Velcro strap to secure the bands; the strap was adjusted to allow both bands to start at approximately the same pressure when the subject’s wrist was still. Figures 2.12 and 2.13 show the test band and data module used in the human subject trials. The test band uses a thin capacitive force sensor (SingleTact) because of its high accuracy, low hysteresis, and easy out of the box use. Note that the data module could be miniaturized but was not required for this experiment and was not focused on.

The subject was asked to perform the following list of activities that a person might encounter during the day.

1. Typing a paragraph at a computer
Figure 2.12: Human subject trials test band with the spring housing attached

Figure 2.13: Human subject trials test band and data module (Arduino writing onto a SD card with an attached RTC) on test subject
2. Wiping down dishes (drying dishes)

3. Finger tapping at different frequencies (.5 hz, 1 hz, 2 hz, 3, hz, 4 hz)

4. Tossing and catching a ball

5. Clapping at different frequencies (.5 hz, 1 hz, 2 hz, 3, hz, 4 hz)

6. Flexing the wrist up and down and holding

7. Making a fist and holding

2.7 Results

Fifteen total tests were performed in this study distributed among ten different research subjects. Pressure data was recorded during the entirety of the test; the individual activities were separated and plotted. Figure 2.14 shows a plot of the test with a tape spring and without a tape spring for each of the eight activities performed for a single subject. Appendix A shows plots for all participants tests. From these plots we can see that wiping the dishes, catching and tossing the ball, and clapping show that the spring mechanism reduces the pressure increase seen performing these actions during the first participants tests. To better understand how well the spring mechanism performs, the mean and standard deviation were calculated for each activity. During some participants’ testing it was noticed that the pressure mean for the test with the spring mechanism increased through some activities. A potential cause of the mean increasing comes from the fact that the spring mechanism does not restrain motion when its total displacement decreases. The mechanism keeps the tension on the sensor but does not keep the sensor in the same position. It is believed that the sensor shifted during the spring testing to rest on a wrist bone which increased the mean pressure. As the mean pressure increased the change in pressure from relative motion increased. The coefficient of variation was calculated to account for this motion in the mean pressure for the spring tests.

Table 2.1 contains the coefficient of variation for all activities of each participant and the combined averages for each activity with and without the spring mechanism. The combined aver-
Table 2.1: This table contains the coefficient of variation for each activity for each participant for both the tests with and without the spring mechanism. The total averaged coefficient of variation and means for all participants is also included.

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<th>Typing</th>
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age helps us see how the spring mechanism performed compared to the control tests without the spring mechanism. On average for all except the typing activity the coefficient of variation is lower for the tests performed with the spring. Figure 2.15 shows the coefficient of variation plotted for each activity for all fifteen tests performed.
2.8 Conclusion and Recommendations

Several design principles have been demonstrated as two main constant-force mechanism designs (tape spring and buckling beams) were developed, prototyped, and evaluated across seven critical design requirements successfully. A human trials test was performed on the WHD with and without an integrated CFM; the band with the CFM on average had a smaller coefficient of variation but most of the error bars had overlap. With the majority of the activities having overlapping error bars we can conclude that while the tape spring reduces the coefficient of variation the reduction isn’t statistically significant for the human trials testing performed. It was noticed that unwanted shifting of the sensor location came from having the CFM integrated into the WHD, but solutions to this problem were not explored as they were outside the scope of this chapter. Future work potentially includes developing a method to restrain the motion of an integrated CFM to one direction to keep the band from shifting, quantifying the pressure on different portions of the wrist during motion, and exploring constant-force mechanisms that would only apply pressure on the sensor to keep constant pressure on a localized spot, rather than being in-line with the band to keep the tension constant.
Figure 2.14: Activities plots for all eight activities performed by participant 1 for both the band with and without the spring mechanism attached. Pressure is in kPa and time is in seconds.
Figure 2.15: Average Coefficient of Variation of all 15 tests for each activity with standard error bars (1. Typing 2. Dishes 3. Tapping 4. Catching 5. Clapping 6. Flex Up 7. Flex Down 8. Fist)
CHAPTER 3. RELATIONSHIPS AMONG BAND TENSION, SENSOR PRESSURE, PATIENT COMFORT, AND PULSATILE SIGNAL QUALITY FOR WRIST WORN HEALTH MONITORING DEVICES

This chapter presents the design and testing of a wrist worn sensing band used to gather relationship data among band tension, sensor pressure, patient comfort, and pulsatile signal quality. A simple mathematical model was developed to show the relationship between pressure on the wrist and tension in the wristband. The model correctly predicts that tension varies linearly with pressure, and that the pressure vs. tension slope increases with increasing wrist width. There also exists a linear relationship between tension and patient pain/comfort, but pressure does not show an effect on the patient discomfort or pain experienced. Signal quality when measured in the range of 0-4 N and 0-20 kPa does not have a direct correlation to either tension or pressure.

3.1 Introduction

The Wearable Health Devices (WHDs) market is rapidly growing. It is projected to reach USD 46.6 billion by 2025 from USD 18.4 billion in 2020 [48]. Wearable Health Devices enable continuous monitoring of vital signs during daily life, while minimizing discomfort and interference with normal activities [8]. There are many different types of WHDs; Jeong and Searson [49] provide a review on existing technologies currently used for measurement of the four primary vital signs: temperature, heart rate, respiration rate, and blood pressure. Dias [8] states nine main valuable vital signs (Electrocardiogram, Heart Rate, Blood Pressure, Respiration Rate, Blood Oxygen Saturation, Blood Glucose, Skin Perspiration, Capnography, and Body Temperature). These papers help show the wide range of possible vital signs that a WHD can monitor. There are also many different types of WHDs in development and currently on the market [50–55]. Due to the broad range of devices and placement on the body we will be narrowing this work to a wristband that will measure skin impedance.
This chapter focuses on four key factors and their relationships that should be considered when designing a WHD: tension in the wristband, pressure on the skin, user comfort, and sensor signal quality. By focusing on these factors and their relationships designers will be able to develop more successful products.

Designing a wristband with a specific tension can be achieved through multiple methods, such as using a constant-force mechanism. By maintaining a constant tension the band will also maintain a near constant pressure on the wrist. By studying the relationship between wristband tension and pressure on the wrist we will be able to determine the desired range of force required from a constant-force mechanism.

Huang and Tan [30] show that there is a relationship between sensor signal quality and band tension. This specific experiment monitors blood pulse waves using a highly sensitive tactile sensing array and tension sensor [56, 57]. They measured pulse waves at band tensions ranging from 3N to 10N with a 1N step increase and found that specific tensions were able to better sense the pulse waves. Multiple studies have been performed using pressure sensors to gather important biometric data [58–62]. Understanding what that tension (and associated sensor pressure) range is and how it correlates to the other factors mentioned above is key to designing a successful wristband WHD.

Quantifying comfort can be difficult. A literature review performed by Pearson [63] looks at 29 studies that used ‘comfort’ or ‘discomfort’ as outcomes. These scales can vary widely from quantifying emotion, attachment, harm, perceived change, movement, and anxiety as comfort metrics [64] to a tool for assessing wheelchair discomfort that contains eight statements related to discomfort and five statements related to comfort that are rated on a seven-point Likert scale [65]. While there are a few tools that use a numerical scale to quantify comfort, we still see a majority of existing papers on WHD using a pass or fail comfort scale. One of the goals of this chapter is to present a comparison between the amount of pressure provided to the band and user comfort.

### 3.2 Modeling Required Tension

To better understand the relationship between pressure on the wrist and tension in a wristband, a simple mathematical model was developed (see Figure 3.1). Two main generalizations were made to simplify the wristband model when finding the pressure $P$. The wrist was approxi-
mated as a circle with a diameter, $D$ (wrist width). The tension $T$, in the wristband was assumed to be constant through the band. Starting with the generalized pressure equation:

$$ P = \frac{F}{A} $$

(3.1)

where the force $F$ is twice the tension in the band and the area is the width of the wrist, $D$, and the width, $w$, of the band. The equation becomes:

$$ P = \frac{2T}{Dw} $$

(3.2)

solving for the slope relationship of tension vs. pressure:

$$ \frac{T}{P} = \frac{Dw}{2} $$

(3.3)

This model gave an early perspective on the linear relationship between pressure and tension that was used in the design of the experiment. The model will be compared to empirical data collected later in this chapter.

Figure 3.1: Model for pressure generated on the wrist from the wristband
3.3 Device Design

Figure 3.2: Picture of the sensing band

Figure 3.2 shows a picture of the sensing band which is composed of three main parts: a tensioner, a force sensor, and a pressure sensor. Each component went through several design and prototype iterations to arrive at the design shown. All stiff parts of the band were 3D printed using Polylactic Acid (PLA) filament and the white flexible bands were 3D printed using Thermoplastic Polyurethane (TPU) filament. The band is clasped together using a Velcro strap. A brief description of the design decisions made for each of the three main components follows.
The primary design requirement of the tensioner was it needed to provide enough travel to accommodate the tension and pressure ranges specified by the study (see the experimental procedure section). A second requirement was it needed to provide continuous variation of the tension rather than discrete steps. The first tensioner used was a hose clamp which was cut, bent, and attached to the band. The hose clamp had two main issues: 1) it would sometimes bind up since it was bent into a shape it was not originally designed for and 2) it was made of rigid metal so it did not easily bend around a user’s wrist. Figure 3.3 shows an exploded rendering of the tensioner device which was created to overcome both of the problems seen with the hose clamp. Additionally, this tensioner is easier to attach to the band and takes up less band real estate. The tensioner is actuated by hand using a hex key wrench. A flexible TPU band was printed to go underneath the tensioner to prevent it from pinching the user's skin.

The force sensor housing consists of two parts which slide past each other and compress a thin-film capacitive force sensor (8mm, 10N SingleTact). SingleTact sensors were used for both the force and pressure sensing units because of their high accuracy, low hysteresis, and easy out of the box use. The main challenge with the force sensor housing was it required two parallel surfaces to come together so the sensor was compressed evenly. To ensure parallel surfaces, the housing needed to be flat and stiff. However, because the wrist is curved, the connecting bands on either side of the housing may apply components of force perpendicular to the sliding motion resulting in only a portion of the tension force being applied to the sensor. To minimize the perpendicular components of force, the overall length of the force sensor housing was reduced through iteration and the band was designed to have the force sensor housing on the top of the wrist which is relatively flat.

Uniform compression of the sensor was also a key design requirement for the pressure sensor. As mentioned previously, the pressure sensing unit also used a SingleTact sensor, but in this case it was a 1N instead of 10N sensor. The sensor was sandwiched between a stiff watch-link type housing and a stiff puck which interfaced with the electrode. SingleTact sensor tails are designed to be able to bend, but repeated or over-bending can shift the layers in the sensor. This shifting can change the calibration and sensor performance. To ensure the same sensor tail bend throughout the tests, a stiff sensor lead covering was attached.
The pressure sensor chip was daisy chained to the force sensor chip which was in turn connected to an Arduino Uno. The Arduino had an LCD screen attached which output the pressure and tension values in real time. During testing, the Arduino was connected to a computer and the pressure and tension values were recorded.

Data from a finger pulse oximeter (PulseSensor.com) and a skin impedance electrode sensor array were also recorded during testing. Both sensors were connected to a Zurich Instruments impedance analyzer and synced with the force and pressure data coming from the wristband. The finger pulse oximeter provided a reference signal for the impedance signal.

![Figure 3.3: Exploded view of the Tensioner](image)

### 3.4 Experimental Procedure

An experiment (IRB2020-268) was developed to gather data to allow the correlation between tension in a wrist band, pressure on the wrist (at the sensor location), impedance pulsatile signal quality, and subject pain/comfort. The participant was asked to remain as still as possible for the entirety of the test to reduce noise from movement. The electrodes were placed over the radial artery, with electrode gel applied to the wrist, and taped in place (see Figure 3.4). The electrode array consists of 16 carbon-infiltrated carbon nanotube electrodes. Each electrode is 5 mm long, 1.5 mm wide, and between 0.3 mm and 0.8 mm tall. Each electrode is segmented into 11 segments, each segment making up 400 um of the total electrode length, with small gaps 60 um wide in between for additional flexibility. The electrodes are adhered to the FPCB with an anisotropic conductive film adhesive (3M 7303), which is conductive up through the tape but not laterally...
across the tape. The adhesive is cured with a simultaneous pressure and heat treatment. Each electrode can be individually addressed through a multiplexer attached between the electrode array and the impedance analyzer, we used 4-point impedance measurements from the impedance analyzer for this test. The electrodes were allowed to acclimate for ten minutes before the test started. The pulse oximeter was placed on the index finger on the same hand as the electrodes. The force and pressure sensors were initialized off the wrist to zero them before the band was put on the subject. The pressure sensor was placed over the electrode array and the band was secured using the Velcro strap. The starting pressure for each test was varied but was kept toward the lower range of pressure (2-8 kPa). Figure 3.5 shows the wristband and sensors being worn by a subject. A timer for a minute and 30 seconds was set for each pressure step, and the tensioner was then adjusted to hit another target pressure. The target pressures were obtained for each specific participant by finding the pressure/tension bounds. We started with the tensioner loose as our lower bound and then tightened half way through the full travel of the tensioner for a second point and then fully tightened the tensioner for the third pressure point. The rest of the data collection points were then randomly selected between the minimum and maximum pressures/tensions. At the end of each minute and 30 seconds the subject was asked to rate their comfort and pain on a scale from one to ten (see Table 3.1). The sampling frequencies used were 16 Hz for the SingleTact (pressure and tension) sensors and 1000 Hz for the impedance analyzer (PPG and Electrodes).

3.5 Results and Discussion

Fifteen total tests were performed in this study distributed among ten different research subjects. Tension in the band, pressure on the wrist (at the electrode location), pulse oximeter, and electrode impedance data were recorded for the full 25 minutes of each test. Each test had either ten or eleven target pressures recorded depending on how long adjusting the tensioner took.

3.5.1 Pressure Vs. Tension

Figure 3.6 shows the tension and pressure for a single participant’s test. The plotted data includes the transitions (initially putting on the test band and tightening/loosening the tensioner).
Figure 3.4: Electrode placed and taped over the radial artery

Figure 3.5: Full wristband data acquisition setup
Table 3.1: Pain and comfort scales ranging from 0 to 10. A comfort of 5 was described as base comfort, or what the research subject would normally wear a watch or wristband at comfortably

<table>
<thead>
<tr>
<th>Value</th>
<th>Pain Description</th>
<th>Comfort Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No Pain</td>
<td>Unbearably Loose</td>
</tr>
<tr>
<td>1</td>
<td>Very Mild</td>
<td>Extremely Loose</td>
</tr>
<tr>
<td>2</td>
<td>Discomforting</td>
<td>Very Loose</td>
</tr>
<tr>
<td>3</td>
<td>Tolerable</td>
<td>Loose</td>
</tr>
<tr>
<td>4</td>
<td>Distressing</td>
<td>Slightly Loose</td>
</tr>
<tr>
<td>5</td>
<td>Very Distressing</td>
<td>Base Comfort</td>
</tr>
<tr>
<td>6</td>
<td>Intense</td>
<td>Slightly Tight</td>
</tr>
<tr>
<td>7</td>
<td>Very Intense</td>
<td>Tight</td>
</tr>
<tr>
<td>8</td>
<td>Utterly Horrible</td>
<td>Very Tight</td>
</tr>
<tr>
<td>9</td>
<td>Unbearable</td>
<td>Extremely Tight</td>
</tr>
<tr>
<td>10</td>
<td>Worst Pain Possible</td>
<td>Unbearably Tight</td>
</tr>
</tbody>
</table>

We can see that the tension and pressure remain fairly consistent during the minute and a half at each step.

The pressure vs. tension with the transitions removed is shown plotted in figure 3.7. There is a linear trend between tension and pressure as we would expect from the model discussed earlier. Only one of the fifteen tests performed is shown in the figure, but all the slope values with wrist measurements are listed in Table 3.2. The rest of the tension vs. pressure plots can be found in Appendix B. The slope values come from a least-squares line fit to the experimental data.

Figure 3.8 plots the measured tension/pressure slope vs the wrist width for the measured data and the model that was developed earlier. A linear fit was applied to the measured data so that the model could be compared. The slope from the model is \(0.01 \, (N/kPa)/(mm)\) vs the \(0.0061 \, (N/kPa)/(mm)\) of the measured data. Both lines show a similar trend, that the larger a wrist diameter the greater the increase in tension required for an equal pressure value. There seems to be an offset from the model and the measured data. We will now explore possible reasons that the model does not match the empirical data.

1. The model assumes the wrist cross section to be a circle whereas the wrist is closer to an oval with a varying cross section over the area the band covered.
Figure 3.6: Tension in wrist band and pressure on the wrist at the sensor location plotted vs. time for a full 25 minute test.

Figure 3.7: Pressure on the wrist at the sensor location vs. tension in the wristband for a full 25 minute test with the transitions removed. A linear fit was used to calculate a slope relationship between pressure and tension.
Table 3.2: Wrist circumference, height, and width data with their respective pressure/tension slopes (slope comes from a linear fit of pressure and tension data points). Note that some participants have multiple pressure/tension slopes and that the slopes slightly differ.

<table>
<thead>
<tr>
<th>Wrist Circumference (mm)</th>
<th>Wrist Height (mm)</th>
<th>Wrist Width (mm)</th>
<th>Tension/Pressure (N/kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>190</td>
<td>45</td>
<td>68.5</td>
<td>0.278241</td>
</tr>
<tr>
<td>150</td>
<td>34</td>
<td>58</td>
<td>0.263829</td>
</tr>
<tr>
<td>160</td>
<td>43</td>
<td>57</td>
<td>0.248095</td>
</tr>
<tr>
<td>190</td>
<td>45.5</td>
<td>68</td>
<td>0.246759</td>
</tr>
<tr>
<td>190</td>
<td>45</td>
<td>68.5</td>
<td>0.241248</td>
</tr>
<tr>
<td>180</td>
<td>44</td>
<td>58</td>
<td>0.174266</td>
</tr>
<tr>
<td>150</td>
<td>34</td>
<td>58</td>
<td>0.158496</td>
</tr>
<tr>
<td>150</td>
<td>31</td>
<td>53</td>
<td>0.152795</td>
</tr>
<tr>
<td>180</td>
<td>48</td>
<td>63</td>
<td>0.142441</td>
</tr>
<tr>
<td>160</td>
<td>40</td>
<td>49</td>
<td>0.136187</td>
</tr>
<tr>
<td>180</td>
<td>44</td>
<td>58</td>
<td>0.127901</td>
</tr>
<tr>
<td>150</td>
<td>34</td>
<td>58</td>
<td>0.105569</td>
</tr>
<tr>
<td>150</td>
<td>37</td>
<td>45</td>
<td>0.082545</td>
</tr>
<tr>
<td>180</td>
<td>48</td>
<td>63</td>
<td>0.067668</td>
</tr>
<tr>
<td>180</td>
<td>62</td>
<td>47</td>
<td>0.058993</td>
</tr>
</tbody>
</table>

2. The tension in the band was assumed to be constant. Friction will exist between the band and the wrist which could provide an inconsistent tension force.

3. The pressure profile of a wrist may not be consistent (i.e. there will be areas with larger forces on the wrist) and this band uses a single pressure sensor.

4. The model does not take into consideration the stiffness of the wrist or any potential restorative forces from the wrist.

5. The model ignores the bending stiffness of the band and assumes that the band perfectly fits the wrist.

Despite the model’s shortcomings, it correctly predicts that tension varies linearly with pressure, and that the pressure vs. tension slope increases with increasing wrist width.

### 3.5.2 Pressure/Tension Vs. Pain/Comfort

Both pressure and tension were compared against pain and comfort. Figure 3.9 shows both pain and comfort vs. pressure on the wrist and tension in the band. The pain and comfort rating...
responses from the participants were binned together from all tests performed. The pressure bins were a range of 1 kPa (0-1, 1-2, 2-3, etc.); the tension bins were increments of .1 N. Standard error was also calculated and is shown in the figure. As we look at the pressure plot we see that there does not seem to be a relationship with how much pressure there is on the sensor location and the comfort of the participant. There is a slight negative slope to the pressure vs pain data set, however it stays close to the no pain value for the full range of pressure. A paper by Dementyev and Paradiso [66] also used a wrist worn device that needed tight contact with the participant’s wrist. They stated that “none of the participants reported discomfort” during their testing. Therefore, our results suggest that pressure in wrist worn devices does not correspond to patient discomfort. The tension in the band, however, shows a slight linear relationship with both patient pain and comfort. This would suggest that increasing pressure on a single spot on the wrist does not affect pain or comfort as much as the total tightness of the band does. With the linear relationship between wrist width and tension/pressure increase we can conclude that the larger the wrist diameter the greater
pain and discomfort a person will experience when compared to someone with a smaller wrist at the same pressure.

Figure 3.9: Pressure on the wrist at the sensor location and tension in the wristband are compared to pain and comfort. Data binning was used for the tension and pressure values (tension in increments of .1 N and pressure in increments of 1 kPa). A linear fit was used to show the trend in the data. a) Pressure vs. Pain and Comfort b) Tension vs. Pain and Comfort
3.5.3 Pressure/Tension Vs. Signal Quality

Pulsatile data was measured through both the PPG sensor attached to the participant’s finger and the impedance electrodes underneath the pressure sensor. Figure 3.10 shows an example with good signal quality, with the pulse clearly visible, and Figure 3.11 shows an example with poor signal quality. The pulsatile data is clearly visible from the PPG sensor for all of the tests performed, and was used as a control signal that the electrode data was compared against.

![Electrode Data](image1)

![PPG Data](image2)

Figure 3.10: Sample pulsatile signals from both the electrode sensors and the PPG this data corresponds to a SQI of .855

The Signal Quality Index (SQI) was calculated by using the peaks from the PPG data and looking for a similar peak pattern in the electrode data. The method used by Jang et al. [67] was slightly modified by using a clean PPG signal to extract the pulses periods instead of relying on electrode data itself to get the periods. A SQI of .6 or greater means that a pulsatile signal is visible, with a .8 or higher representing an extremely defined signal. The pulsatile signal in figure 3.10 represents a SQI of .855 and the pulsatile signal in figure 3.11 has an SQI value of .135. The SQI was calculated for each tension and pressure step and are shown in Figure 3.12. These plots suggest that there is not a direct correlation between SQI and pressure or tension. Work done by Haung et al. [30] showed that visible blood wave pulses were more clear with certain strap tensions (5-9 N).
Figure 3.11: Sample pulsatile signals from both the electrode sensors and the PPG this data corresponds to a SQI of .135

and less visible/not visible at tensions outside that range. The tension range that we operated in was 0-4 N and we saw a wide range of SQI values. There is a possibility that a larger SQI would be seen at the tension range Haung explored or if a higher current was used (which could lead to a higher signal to noise ratio) to measure impedance. However, higher tension would also likely contribute to more pain and discomfort.

3.6 Conclusion and Future Work

In conclusion we see that there exists a linear relationship between tension and pressure, the tension/pressure slope values and wrist width, and tension and pain/comfort. Pressure does not have an effect on the patient discomfort or pain experienced. The signal quality does not seem to have a direct correlation to tension or pressure when measured in the range of 0-4 N and 0-20 kPa respectively.

Potential future work includes three main improvements. First, we recommend developing a more exact mathematical model for the tension and pressure relationship by including actual wrist geometry rather than modeling it as a circle, and including wrist stiffness and material properties. Second, performing another pain and comfort study where the time at each tension and pressure
is extended from one and a half minutes would allow for a better representation of how pain and comfort at certain pressures and tensions for longer periods affect patient perception. Lastly, we suggest performing another study where the current used in the electrodes is increased for a better signal to noise ratio and exploring a larger range of band tension.
CHAPTER 4. CONCLUSION

In response to the growing Wearable Health Devices industry, this research focused on developing key design requirements to help in the design of constant-force wristbands. These seven critical design requirements are: mechanism size vs. allowable travel, ability to be used on a curved surface, works well with existing clasps, ease of assembly, direction of travel, material, and force generation. Two main constant-force mechanism designs (tape springs and buckling beams) were developed, prototyped and evaluated across the seven critical requirements. A human trials test was performed on a WHD with and without an integrated CFM.

The buckling beams concept was based on the fact that beams in buckling produce a near constant force. This design performed well in four of the seven requirements (ease of assembly, direction of travel, material, and force generation). The main drawback of the buckling beams concept is the difficulty to be used on a curved surface and the mechanism size vs. allowable travel. The buckling beams mechanism was not taken past the initial prototyping stage, however, two concepts were generated that would allow buckling beams to be used in a wrist worn wearable health device. First, by constraining the mechanism to the top or bottom of the wrist we remain fairly horizontal. The second concept was to integrate a buckling beams mechanism into a tri-fold clasp that will keep the mechanism constrained.

The tape spring performed equally or outperformed the buckling beams mechanism in all but the ease of assembly requirements. Due to this, the tape spring was chosen as the constant-force mechanism used in the human trials testing. While the mean values of the coefficient of variation were on average lower for the tests performed with the spring with the overlapping error bars the result cannot be consider statistically significant. Some unexpected difficulties were seen, but were not further explored because they fell outside the scope of this work.

Work was also done on understanding four key factors and their relationships that should be considered when designing a WHD: tension in the wristband, pressure on the skin, user com-
fort, and sensor signal quality. By focusing on these factors and their relationships, designers will be able to develop more successful products. Human trials testing on ten different research subjects were carried out to gather empirical data for correlation. A simple mathematical model was developed for the relationship between pressure on the wrist and tension in the band; this model also helps understand how the pressure/tension slope changes with wrist size.

The model correctly predicts a linear relationship between pressure on the wrist and tension in a wristband, and that the pressure vs. tension slope increased with increasing wrist width. Understanding this linear relationship helps designers know that if tension in the wristband is controlled, participants with different wrist sizes will experience different pressures at the same tension value. The pain and comfort responses were compared to both the pressure and tension data collected from the wrist worn sensors. The pressure vs. comfort/pain plot showed that there wasn’t a correlation between pressure at the sensor location and comfort of the participant; there was a slight negative slope to the pressure vs. pain data set but it stayed around the no pain value for the pressures tested. The tension in the band showed a slight linear relationship with both patient comfort and pain. This data suggests that a person will experience less irritation from a direct application of pressure than that of a total increase in band tightness (tension). The signal quality does not seem to have a direct correlation to tension or pressure when measured in the range of 0-4 N and 0-20 kPa respectively.

Future work includes six main improvements or further exploration. The first suggestion is to design a method that restrains the motion of an integrated CFM to one direction to keep the band from shifting. Second, by quantifying the pressure on different locations of the wrist during motion we can better understand the intricacies pressure experiences due to movement. Third, rather than looking at constant-force mechanisms that increases the total tension in the band, developing constant-force mechanisms that will only apply pressure at the sensor location can lead to avoiding potential patient discomfort. The fourth improvement suggestion is to develop a more exact mathematical model for the tension and pressure relationship by including actual wrist geometry rather than modeling it as a circle, and including wrist stiffness and material properties. Fifth, is performing another pain and comfort study where the time at each tension and pressure is extended from one and a half minutes, this would allow for a better representation of how pain and comfort at certain pressures and tensions for longer affect patient perception. Lastly, performing
another study where the current used in the electrodes is increased for a better signal to noise ratio and exploring a larger range of band tension and sensor pressure.

The contributions of this research include novel integrated constant-force mechanism wristbands, which resulted in patentable wristband mechanism designs. Design requirements were presented to help in the design of constant-force wristbands with examples of the design process, and a better understanding of the complexity that comes from designing wearable medical devices with integrated CFMs. This research also provided correlation data and a better understanding of tension in the wristband, pressure on the skin at the sensor location, user comfort, and sensor signal quality.
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APPENDIX A. MOVEMENT ACTIVITY DATA

Appendix A contains activities plots for all eight activities performed by each participant for both the band with and without the spring mechanism attached. Pressure is in kPa and time is in seconds.

Figure A.1: Data for participant 1
Figure A.2: Data for participant 2
Figure A.3: Data for participant 3
Figure A.4: Data for participant 4
Figure A.5: Data for participant 5
Figure A.6: Data for participant 6 (test 1)
Figure A.7: Data for participant 6 (test 2)
Figure A.8: Data for participant 7 (test 1)
Participant 7: Test 2

Figure A.9: Data for participant 7 (test 2)
Figure A.10: Data for participant 8 (test 1)
Figure A.11: Data for participant 8 (test 2)
Figure A.12: Data for participant 9 (test 1)
Participant 9: Test 2

Figure A.13: Data for participant 9 (test 2)
Figure A.14: Data for participant 10 (test 1)
Figure A.15: Data for participant 10 (test 2)
Appendix B contains plots for pressure on the wrist at the sensor location vs. tension in the wristband for a full 25 minute test with the transitions removed for each participant. A linear fit was used to calculate a slope relationship between pressure and tension.

Figure B.1: Data for participant 1
Figure B.2: Data for participant 2
Figure B.3: Data for participant 3
Figure B.4: Data for participant 4
Figure B.5: Data for participant 5
Figure B.6: Data for participant 6 (test 1)
Figure B.7: Data for participant 6 (test 2)
Figure B.8: Data for participant 7 (test 1)
Figure B.9: Data for participant 7 (test 2)
Figure B.10: Data for participant 8 (test 1)
Figure B.11: Data for participant 8 (test 2)
Figure B.12: Data for participant 9 (test 1)
Figure B.13: Data for participant 9 (test 2)
Figure B.14: Data for participant 10 (test 1)
Figure B.15: Data for participant 10 (test 2)
Figure B.16: Data for participant 10 (test 3)