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14. ABSTRACT The clinical literature indicates that performing a push up or pressure relief every fifteen minutes for two minutes or more can reduce the likelihood of developing pressure injuries. There has been little research to develop technology interventions to promote behavioral changes among manual wheelchair users (MWU) to promote active sitting and regular pressure relief (PR). The objective of the project is to further develop and evaluate the Manual Wheelchair Virtual Coach (MW-VC). This system has been developed consisting of sensors, artificial intelligence (AI) algorithms, and a user interface that tracks manual wheelchair users' changes in seated position, and coaches them to perform effective pressure reliefs. The entire system was updated based on the feedback received from individuals with spinal cord injury (SCI) enrolled in focus groups, usability testing and pilot study. Overall, participants rated the MW-VC highly for innovation, usefulness, and compactness.					
15. SUBJECT TERMS Pressure injury, Spinal cord injury, Center of Pressure, Pressure relief, Pressure sensors					
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1. INTRODUCTION:

Pressure injuries (PI) are tremendous problems for individuals with mobility and sensation impairments; harming independence, quality of life and costing over \$50,000 for treatment. There has been little research to develop technology interventions to promote positive behavioral changes among manual wheelchair users to promote active sitting and regular pressure relief. Moreover, there is no "one size fits all" solution because each person has individual needs that require to be communicated between the person and their seating clinician. The objective of the project is to further develop and evaluate the Manual Wheelchair Virtual Coach (MW-VC). This system consists of (1) sensors that accurately track the seated positions of manual wheelchair users, (2) an algorithm that interprets the data and (3) provides instructions/guidance on pressure relieving exercises via software application installed on a cellphone. In the first year, we focused on expert system and machine learning algorithms as well as developed testing prototypes. Fabrication techniques for the mechanical components were developed and refined before integration into the system for preliminary testing. In the second year, software application was enhanced, and usability testing of the system was conducted with individuals with spinal cord injury (SCI) who used manual wheelchairs. The artificial intelligence (AI) has potential to identify pressure relief activities to tailor messaging to user.

2. KEYWORDS:

Pressure injuries, Spinal cord injury, Pressure relief, Force sensors, Artificial Intelligence

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: To obtain a record of MW seated CoP patterns during usage by PwSCI and to relate that to surveys of activity, participation, and seating discomfort.

Specific Aim 2: To determine if virtual coach features of the MW reduce seating discomfort and improve adherence to CPG.

Major Task 1: Institution Approvals and Data-Safety & Monitoring	Timeline months	Percentage completed
Coordinate DoD 2nd level IRB review (ORP/HRPO)	2-5	100%
Submit PITT IRB amendments, adverse events and protocol deviations as needed	1-12	100%
Submit annual IRB report for continuing review	12	100%
<i>Milestone Achieved: All human subject approvals on file</i>	3	100%
Major Task 2: Development Specific Aim 1 (DSA-1): Expert system and machine learning algorithms. (Completed in year 1)		
Subtask1: Expert System Algorithms		
Identify relationships between body characteristics and CoP for PR	1-3	100%
Simulate expert learning algorithms in MatLab achieve 90% success rate	1-4	100%
<i>Milestone Achieved: Expert system algorithms completed</i>	4	100%
Subtask 2: Machine Learning Algorithms		

Test and validate machine learning algorithms using MatLab	3-5	100%
<i>Milestone Achieved: Machine learning algorithms able to correctly detect active sitting 80% of the time without human intervention</i>	6	100%
Major Task 3: <u>Development Specific Aim 2 (DSA-2): Design and implementation of the MW-VC application software.</u>		
<i>Subtask 1: Application software graphical user interface</i>		
Write and test for operability of the user interface	1-3	100%
<i>Milestone Achieved: GUI user interface operational</i>	3	100%
<i>Subtask 2: Application software cloud connectivity</i>		
Write and test code for cloud connectivity	1-3	100%
<i>Milestone Achieved: Cloud connectivity software completed</i>	3	100%
<i>Subtask 3: Application software contextual awareness algorithms</i>		
Write and test code for contextual awareness algorithms	1-3	40%
<i>Milestone Achieved: Contextual awareness software completed</i>	3	60%
<i>Subtask 4: Application software ecological momentary assessment</i>		
Write and test code for ecologic momentary assessment algorithms	1-4	100%
<i>Milestone Achieved: Ecological momentary assessment software completed</i>	4	100%
<i>Subtask 5: Application software for behavioral coaching</i>		
Write and test code for behavioral coaching	1-4	100%
<i>Milestone Achieved: Behavioral coaching software completed</i>	4	100%
Major Task 4: <u>Development Specific Aim 3 (DSA-3): Design, prototyping, calibration MW-VC.</u>		
<i>Subtask 1: Affordable seating system sensing package – design (Completed in year 1)</i>		
Create CAD and CAM files from mechanical and electronic components	1-2	100%
<i>Milestone Achieved: Complete solid models, drawings, parts-list</i>	2	100%
<i>Subtask 2: Affordable seating system sensing package - prototype</i>		
Create and refine prototype from mechanical and electronic components	1-3	100%
<i>Milestone Achieved: Complete working prototypes for 3 wheelchairs</i>	3	100%
<i>Subtask 3: Affordable seating system sensing package – calibration and validation</i>		
Calibrate, validate, and refine prototype	3	100%
<i>Milestone Achieved: Complete working prototypes for 3 wheelchairs</i>	3	100%
Major Task 5: <u>Development Specific Aim 4 (DSA-4): Conduct usability testing for Specific Aims 1-3.</u>		
<i>Subtask 1: Conduct usability testing</i>		
Recruit and enroll participants	1-3	100%
Conduct focus group with MW-VC (<i>Completed in year 1</i>)	6	100%
Refine design	2-5	100%
<i>Milestone Achieved: Usability study completed and design refined</i>	5	100%
Major Task 6: <u>Development Specific Aim 5 (DSA-5): Conduct a Pilot Clinical Trial.</u>		

Subtask 1: Pilot Study		
Coordinate all study steps, data collection and database requirements	4	100%
Finalize assessment measurements	4	100%
<i>Milestone Achieved: Pilot Study begins</i>	6	100%
Recruit participants and complete protocol (N=10)	6-10	80%
<i>Milestone Achieved: Report findings from Pilot Study</i>	10	80%
Subtask 2: Determine modifications to protocol that are needed to implement larger scale study		
Revise protocol, instruments, and measures	11	100%
<i>Milestone Achieved: Protocol finalized</i>	12	80%
Major Task 7: Data Analysis		
Subtask 1: Monitor data collection rates and data quality		
Perform analyses, share output and findings with all investigators	11-12	60%
Dissemination of findings (abstracts, presentation, publications, DOD)	11-12	60%
<i>Milestone Achieved: Report results from data analyses</i>	12	70%
Major Task 8: Development Specific Aim 6 (DSA-6): Write proposal for MW-VC Clinical Trial. (Completed in year 1)		
Subtask 1: Prepare submission of proposal for clinical trial	12	100%
<i>Milestone Achieved: Grant proposal submitted</i>	12	100%

What was accomplished under these goals?

Work related to: Major task 1

Accomplishment #1: Institution approvals and Data safety & monitoring

- **Specific Objectives:**

- Coordinate DoD 2nd level IRB review (ORP/HRPO)
- Submit PITT IRB amendments, adverse events and protocol deviations as needed.
- Submit annual IRB report for continuing review

- **Major Activities:**

- 1) All human subject testing was conducted according to the approved Pitt IRB protocols. These IRBs were renewed annually to ensure compliance with the university policies.
- 2) No adverse events or protocol deviation were reported. However, necessary amendments were submitted in order to keep up with the overall project timeline.

- **Significant Results:**

All human subject approvals are on file and necessary Pitt IRB and DoD approvals were received to conduct all the phases of this research study and respective continuing reviews have also been approved.

Work related to: Major task 2

Accomplishment #2: Expert system and machine learning algorithms.

- **Specific Objectives:**

- Identify relationships between body characteristics and CoP for PR
- Simulate expert learning algorithms in MatLab achieve 90% success rate
- Test and validate machine learning algorithms using MatLab

- **Major Activities:**

1. During the first project year, relationship between Center of Pressure (CoP) and seated position was established for left, right, and forward leaning pressure relief maneuvers based on data collected from a previous protocol where two clinicians classified sixteen participants as active sitting behavior and thirteen as passive. An algorithm based on decision trees was developed to discriminate between the types of PR. The collected load cell data were converted to CoP. The sampling rate was 1000Hz. However, to establish a classifier for real-time use, the data were down sampled to 1Hz. As shown in Figure 1, the blue and yellow lines are the CoP data of 200 seconds and the red circles are the down-sampled data.

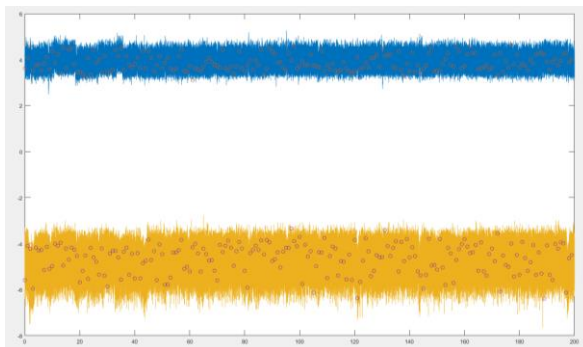


Figure 1: The original and down-sampled CoP data

To be able to provide enough samples for learning, various learning window sizes were tested: 2, 5, 10, 30, 60, 90, 120, 150, 180 seconds. Four machine learning algorithms were used to establish a machine learning classifier: complex decision tree, bagged decision tree, fine KNN, and SVM. The sitting behaviors of twenty-nine participants whom the clinicians classified were used as the ground truth for training the classifier. Figure 2 shows the accuracy of different learning windows. The Fine KNN achieved 100% accuracy with a 5-second learning window and others achieved

100% with a 60-second learning window. A MatLab program was developed to down-sample CoP data, select data using learning window size, establish ground truth dataset, train machine learning classifier, test accuracy of classifiers, and classify sitting behaviors. Figure 3 shows one example of the decision trees with 100% accuracy. It used the weight range, jerk angle, mean acceleration, angle minimum, and x-axis velocity to classify the sitting behavior.

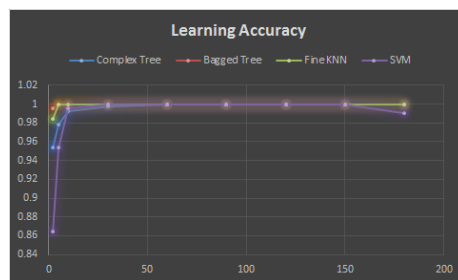


Figure 2: Accuracy of the machine algorithms.



Figure 3: One example of the decision trees with 100% accuracy

	Rater AK	Rater RC	Classifier (Complex Tree, 1Hz, win:60s)	Classifier (BaggedTree, 1Hz, win:60s)	KNN	SVM	Total
MW-VSC #1	A	P	1	1	0.011765	0	0.502941
MW-VSC #2	A	P	1	1	1	1	1
MW-VSC #10	A	P	1	1	1	1	1
MW-VSC #13	P	A	1	1	1	1	1
MW-VSC #14	P	A	0	0	0	0	0
MW-VSC #16	P	A	1	1	1	0.588235	0.897059
MW-VSC #17	P	A	1	1	1	1	1
MW-VSC #18	A	P	0	0	0	0.641176	0.160294
MW-VSC #19	A	P	1	1	1	1	1
MW-VSC #20	P		1	1	0.925	0.654545	0.894886
MW-VSC #27		??	1	1	1	1	1
MW-VSC #35	P	A	0.814286	0.964286	1	1	0.944643
MW-VSC #40		??	0.292857	0	1	0.492857	0.446429
	Active: 5	Active: 5				Active: 7	Active: 9
	Passive: 6	Passive: 5	Active: 10	Active: 10	Active: 10	Passive: 2	Passive: 2
	No data: 2	No data: 3	Passive: 3	Passive: 3	Passive: 3	Unknown: 4	Unknown: 2

Table 1: Machine Learning algorithms applied on the disagreed data

We achieved 100% accuracy on the sitting behaviors of twenty-nine participants whom the clinicians classified in concordance. In order to further examine the difference between classifiers, the data of thirteen participants that clinicians had disagreements or did not rate were classified with the four classifiers as shown in Table 1. Most classifiers tended to rate active than passive but the SVM was less optimistic. All classifiers showed evenly agreement and disagreement with both clinicians. In the combination of all the classifiers, the disagreement of classifiers between decision tree and KNN and SVM on the participants #1 were smoothed. As the algorithms will be used for training and coaching the sitting behavior and pressure relieving exercises, positive responses would be better because they facilitate to encourage the users to practice and keep the active sitting behavior. As the algorithms provided the likeliness of active/passive sitting behavior, some participants were rated between 0 and 1, which is in concordance with the disagreement of the clinicians' judgment. It might have been because it is difficult to make clinical judgments on the occasional active sitting actions. The classifiers showed the percentage of active sitting behavior during the testing period which can be used as a scoring system to help the user maintain healthier sitting behavior.

- In the subsequent quarters, we continued refining the decision tree method for classifying the types of pressure relief, based on input from clinicians, and calibrated against a pressure mat as a clinical standard. In order to provide a self-learning interface during system set up — a feature asked for by some clinicians — we also developed a classifier using K-means Clustering. Improvement was made to ease the pressure relieving exercise parameters setup. Instead of setting up by inputting the distance of center of pressure, a learn-by-demonstration program was developed so that the clinician could ask the wheelchair user to perform the pressure relieving exercise and the program will compute the boundaries and thresholds.
- PR determination based on the previously defined algorithm was incorporated into the software application to trigger the PR timer when the magnitude of change in center of pressure exceeded a specified value.

4. Figure 4 shows that the signal increases as the center of pressure moves further away from the center of the supporting cross piece. However, as the CoP moves outside of the supporting cross piece, the signal begins to decrease. This behavior was not observed in the previous prototype based on complementary strain gages bonded to the members of the cross piece. Possible causes were investigated including preloading of the load cells during assembly and calibration, or nonlinear behavior from the member of each pair of load cells that would be in tension at these extreme displacements overwhelming the signal from the member that is in compression. Possible solutions were also identified to address the issue by increasing the number of analog-to-digital conversion channels and summing the responses in the digital rather than the analog domain.

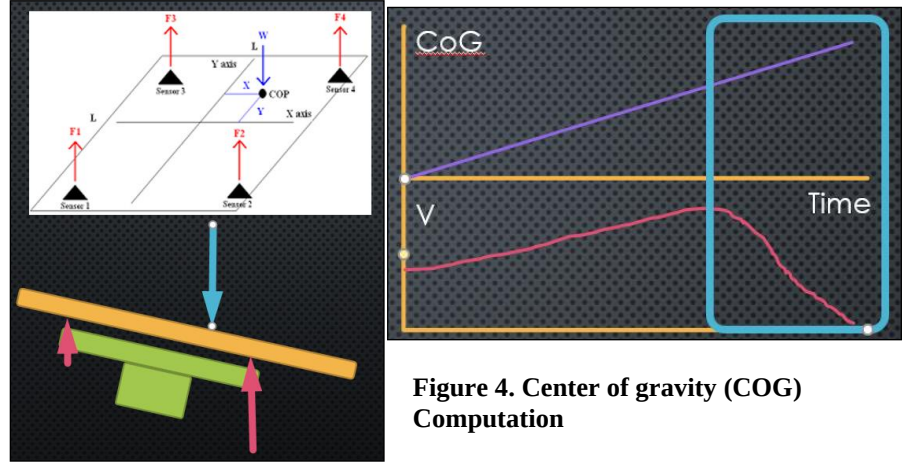


Figure 4. Center of gravity (COG) Computation

5. *Pressure Relief Cluster Analysis Classification:* To refine the classification algorithm, in order to categorize more types of pressure relief behavior, a cluster analysis was performed on data from the first scoping study while 20 manual wheelchair users performed forward, leftward, and rightward leans, posterior leans (sliding forward on the seat and putting weight on the sacral area and on the backrest), and push-ups. Data from all participants performing all five types of pressure reliefs was entered into a single array. The independent variables in the analysis were center of pressure X, center of pressure Y, and percent of participant's weight (the last variable divided by four in order to scale it relative to the center of pressure values). The K-Means function in Matlab was used with a target of 6 clusters. K-Means clustering is an unsupervised machine learning technique that attempts to partition the data into a given number of clusters by minimizing the mean distance between data points within a cluster. Figure 5A displays the individual center of pressure data points on X – Y axes that correspond to observing the wheelchair seat from above, with the top of the graph representing the front edge of the seat. Figure 5B shows the position of each cluster centroid in the X, Y, and percentage of weight coordinates.

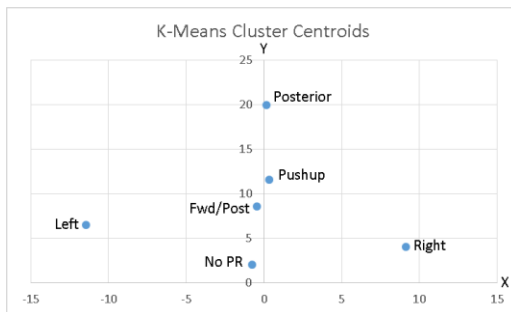


Figure 5A. K- Means Cluster Centroids (2D)

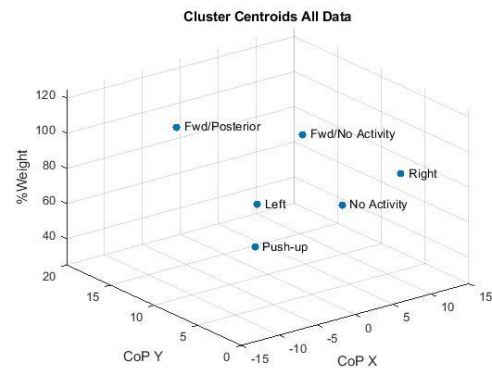


Figure 5B. K- Means Cluster Centroids (3D)

6. The following table shows the centroids of each cluster in the X, Y, and weight dimensions, as well as the percentage of time that subjects spent in each area while the pressure reliefs were being recorded. For example, when subjects were asked to do leftward then rightward pressure reliefs, it would be expected that a portion of the data would be classified as no activity, a portion as a leftward lean, and another portion as a rightward lean. A much smaller percentage of the time would be expected to be categorized as other types of pressure relief — e.g. forward pressure relief as the subject moves from left to right. From these assumptions, and the physical position of each centroid, it is possible to assign a label to each cluster corresponding to the type of pressure relief it most likely represents. This method demonstrates good discrimination between no activity, leftward, rightward, and push-up pressure reliefs. However, it shows a significant amount of overlap in the data representing forward and posterior leans. This result is not unexpected, as both forward and posterior leans shift the subject's weight significantly forward on the wheelchair's seat.

X	Y	%W/4	Forward	Left-Right	Posterior	Pushup	Conclusion
9.13219	4.015236	24.5926	2.845849	20.69064	1.7506	0.52514	Right
-0.46656	8.597641	24.02792	31.27755	7.627156	23.8104	15.3459	Fwd/Post
0.182041	19.94595	17.73992	6.895094	0.171743	30.1936	3.32724	Posterior
-11.4269	6.500693	22.14447	0.104151	20.78789	0.4118	0.06686	Left
0.341948	11.59009	4.7099	1.516038	1.563303	3.8132	24.7482	Pushup
-0.75442	2.045854	24.45414	57.36132	49.15927	40.0204	55.9867	No PR

Pushup threshold = 58.0320% of subject weight

• Significant Results:

A cluster analysis of data taken as manual wheelchair users performed side, forward, and backward leaning pressure reliefs, as well as push-ups, were observed to be separable into at least 5 groups that logically corresponded with neutral sitting, leftward lean, rightward lean, push-up, and a group that showed similar data for forward and backward leans. The colors in the figure 5C correspond to the division of points into 6 clusters — neutral sitting, leftward lean, forward lean, rightward lean, backward lean, and push-up. The relationships among the centroids of these clusters (center of each cluster of data in the coordinate system) were incorporated into an algorithm to classify pressure relief maneuvers based on the user's center of pressure and total weight as measured by the instrumented wheelchair seat pan. Thresholds for the degree of leaning and duration of lean or push-up that constitutes an effective pressure relief were determined by reviewing literature on the topic and consulting with clinicians with expertise in wheelchair seating. The first

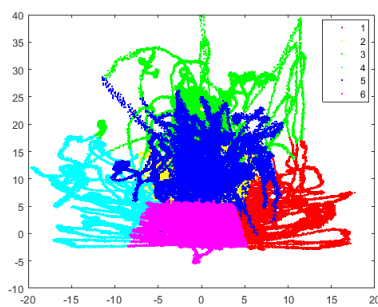


Figure 5C

algorithm implemented in the MW-VC only incorporated forward and sideways leaning pressure reliefs. It did not always recognize and classify pressure reliefs correctly for the initial group of subjects. Subsequent examination of the data has suggested a different calibration method — with the subject in the wheelchair. Push-ups will either be added as a separate pressure relief category for the remaining subjects in this study, or in a subsequent study. A mathematical model that accounts for the angle of the wheelchair seat relative to gravity — e.g. when the wheelchair is on a slope — has been developed, and will also be incorporated into future versions of the MW-VC, as part of contextual awareness.

Work related to: Major task 3, Subtask 1-5:

Accomplishment #3: Design and implementation of the MW-VC application software

- **Specific Objectives:**

- Write and test for operability of the user interface
- Write and test code for cloud connectivity
- Write and test code for behavioral coaching

- **Major Activities:**

- 1) In the first quarter of year 1, the primary User Interface version 1.0 was completed, along with sub-activities within the phone application. Interface testing was completed for all version 1.0 interfaces that were developed. Bluetooth communication between hardware and phone app was established and tested. Animation of communicated CoP was achieved and demonstrated. Basic Application architecture for redesign of Android Application was completed. Simple Firebase Real-Time Database for data management and authentication was implemented. *Firebase* is Google's mobile platform that helps quickly develop high-quality apps. Behavioral coaching was developed and tested as well.
- 2) In the subsequent months, a basic structure of the data collection tool was implemented. The *Tool for Assessing Wheelchair discomfort (TAWC)* was used during usability testing to assess user discomfort related to the wheelchair sitting activity. The TAWC was used to assess the participants' wheelchair seating discomfort levels with MW repositioning (seated time, movement of CoP, weight distribution, and frequency of pressure relief). The TAWC provides General Discomfort Score and a Discomfort Intensity Score.
- 3) In the third and fourth quarter of year 1, we created an Android app interfaced to an “Android Things” board, an Android-based embedded operating system platform by Google. It supports Bluetooth low energy as well as Wi-Fi. It includes APIs that provide low level I/O and libraries for common components like temperature sensors, display controllers, and more. The Android Things platform allows for seamless integration with the cell phone application and reliable wireless connectivity. It also eliminates the need for kernel development and greatly simplifies firmware development needed for peripherals. Artificial intelligence algorithms were incorporated into the Phone App. The below figure shows the first version of the User menu, Pressure reliefs screen, Performance summary data and Clinician parameters settings, see Figure 6.

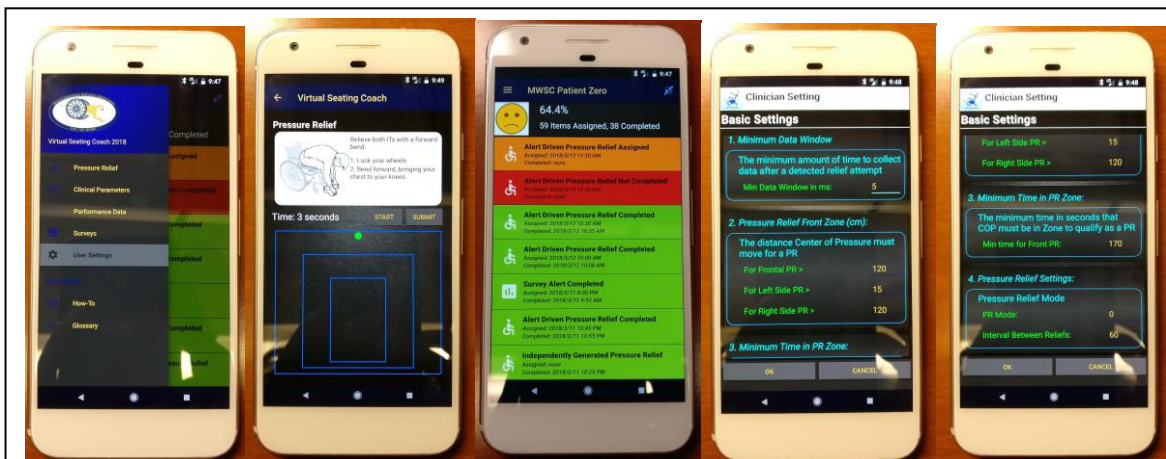


Figure 6. (Version 1): Screen shots for the User menu, Pressure reliefs screen, Performance summary data, and Clinician parameters settings.

- 4) In the first quarter of year 2, we continued software development on the Android Things. Figure 7 below shows the development environment. The development tool provided real-time monitoring of the CPU, memory, network, and energy usage while the application was running on the device. We used this to visualize the coding process and identify the event handling. This also allowed us to optimize the app performance and battery life.

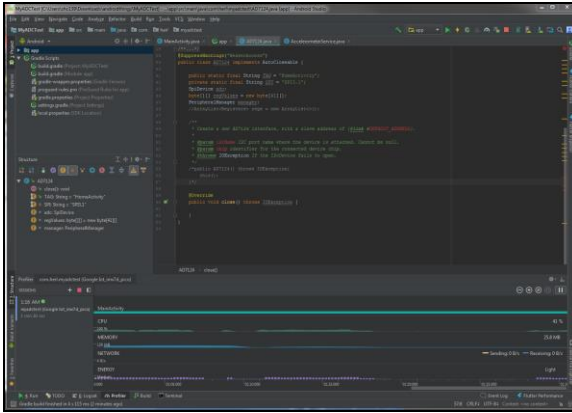


Figure 7. Android Things development environment



Figure 8. Android Things onboard display

- 5) Figure 8 shows the Android Things PICO Pi IMX7 board with onboard display and the ADC connected to testing analog input source. The onboard LEDs and segment display was used to show the app status. The green LED shows the sampling of the load cell voltages. The blue LED indicates the Bluetooth connection to the smartphone and the red LED flashes when an error occurs. Peripheral hardware test for the onboard sensors and general-purpose inputs and outputs (GPIOs) were performed. The ADC driver for the mikroBUS of the PICO Pi IMX7 were created and tested the connection for reliability and accuracy.

- 6) The smartphone application was improved to include the latest graphic user interface (GUI) material design which provided better visibility to the contents and simplified interactions. Figure 9 shows the layouts of the material design.

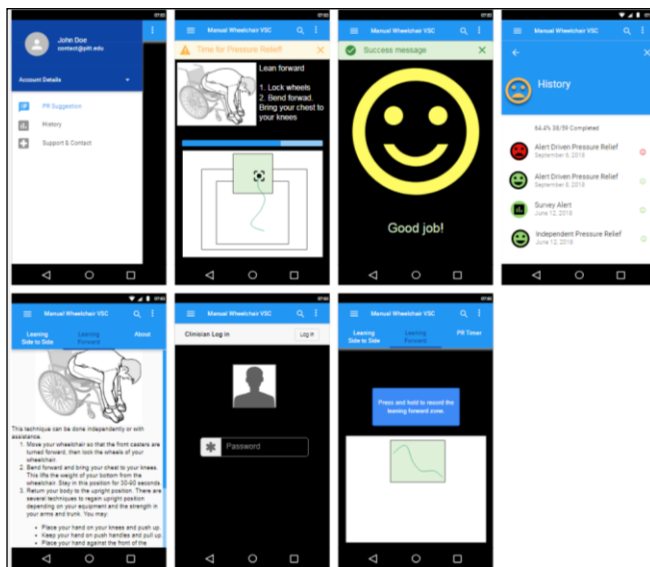


Figure 9. (Version 2): Smartphone app component layouts

The pressure relief page was simplified to reduce the number of tapping. The help menu of pressure relief was improved allowing better flow in viewing the information. Several tests were performed such as Bluetooth connection to the Android Things, cloud connection, data integrity for the behavioral coaching to ensure the robustness of application and data security for the long-term trial.

- 7) In the following quarter, the smartphone application was further improved to include the latest graphical user interface (GUI) material design (Flutter by Google). Figure. 10 shows the layouts of the material design. The pressure relief page shows the relieving area and instructions of the relieving technique with a picture. The moving circle indicates the center of gravity on the seat which helps the user to shift weight correctly. A countdown timer under the circle helps the user know the remaining time left in this position. When sliding from the left side of the screen, there is an additional menu of reviewing performance data, changing clinical parameters and settings, and finding contact information. On the top of the screen, the Bluetooth icon shows the Bluetooth connection status. The information icon on the top right corner of the screen is the help menu that contains articles about the importance of performing pressure relieving exercises. Moreover, the data related to notification and reminders were successfully uploaded to the Firebase database as shown in Figure. 12, this data shows when the user received the reminder, when the pressure relief exercise was completed, how many times the user was notified and completed PR, etc. Figure. 11 shows a flowchart of the Server based computing and Figure. 13 shows MWVC Framework.

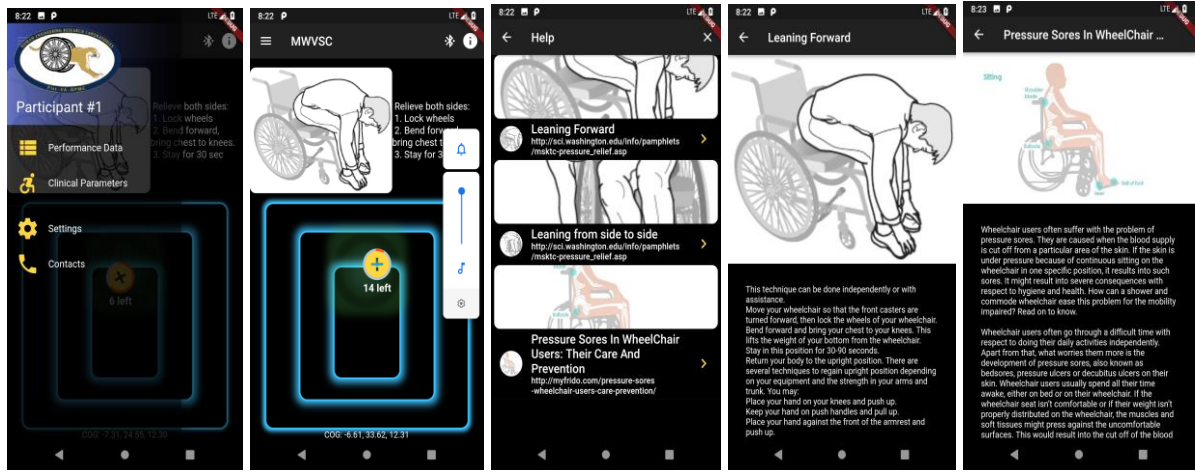


Figure. 10 (Version 3) Smartphone app component layouts

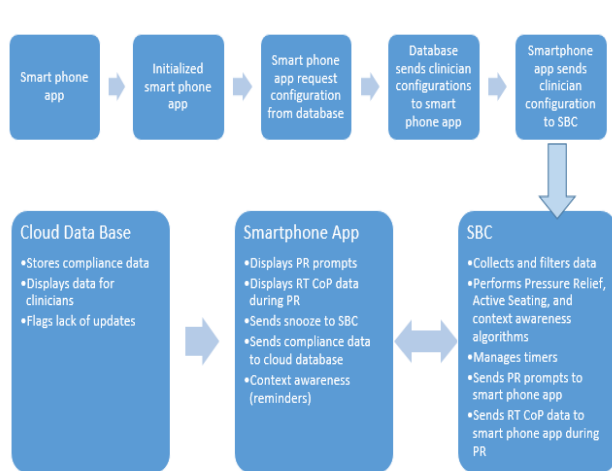


Figure 11. Server based computing (SBC) flowchart

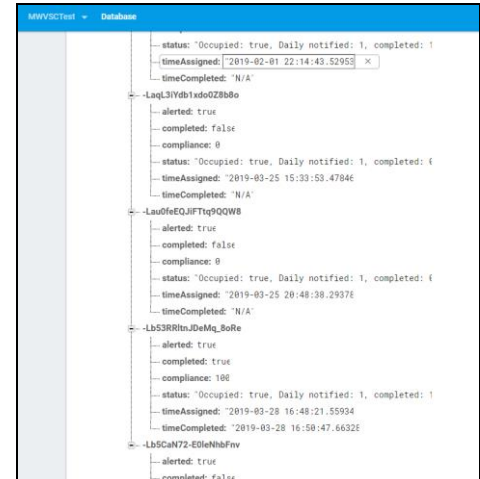


Figure 12. Firebase Database of the reported notifications and reminder

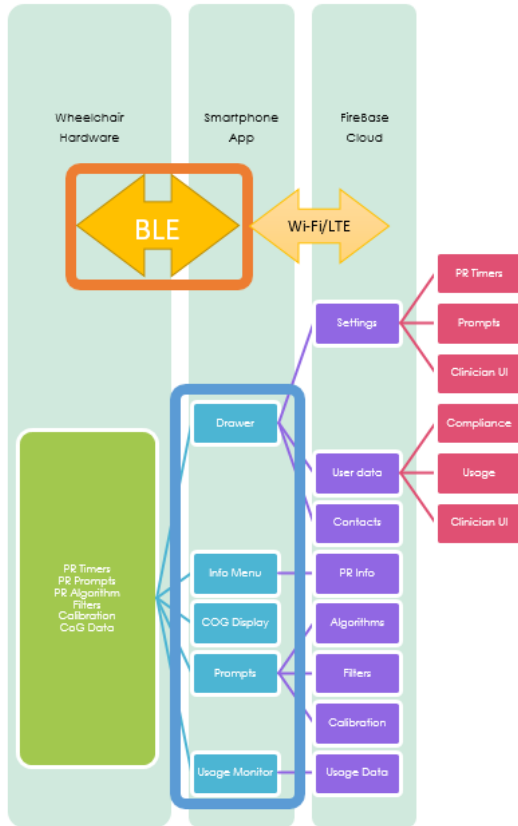


Figure. 13: MWVC Framework



Figure. 14: (Version 4): Application on cellphone

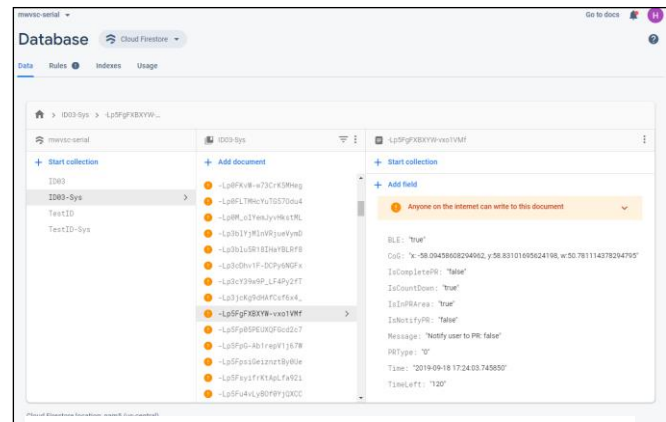


Figure. 15: Database for remote monitoring

- 8) In the initial quarters of year 2, we almost finalized the mobile application for the presentation of the CoP, coaching for pressure relieving exercises, detection of pressure relief types, data collection, and activity sharing to the cloud. In Figure. 14, the CoP is shown as the yellow circle that represents the location on the seat which is the rectangle. There are five portions on the seat that represent areas related to the pressure relieving exercises; the top triangle area is the location that produces effective forward lean pressure relief (PR). The two triangular areas on the sides are the effective side leans. The bottom black triangle area is the back of the seat and the central dark circle means the area does not qualify as PR. The PR areas turn green when the CoP is inside the effective area and the timer will start to show the seconds that the user must remain in this position. On top of the CoP interface, a picture and short description help to guide the user complete effective PRs. The application will upload the usage and movement to the cloud storage. We continued to use Firebase (Figure. 15). It includes the system messages, CoP, PR completion, PR type, PR time, and BLE connection.
- 9) Finally, in the last quarter, Android application was upgraded to include additional GUI components including the progress chart and dashboards, as shown in Figure 16. This dashboard was developed using card widgets with fl_chart plugin in the flutter, the framework to develop Android

applications. These dashboard GUI design helps to track the repositioning exercise history and status. The overall daily progress shows the compliance and the cards shows weekly and daily progress of the repositioning exercises. The GUI was connected to the Firebase database and evaluated for stability.

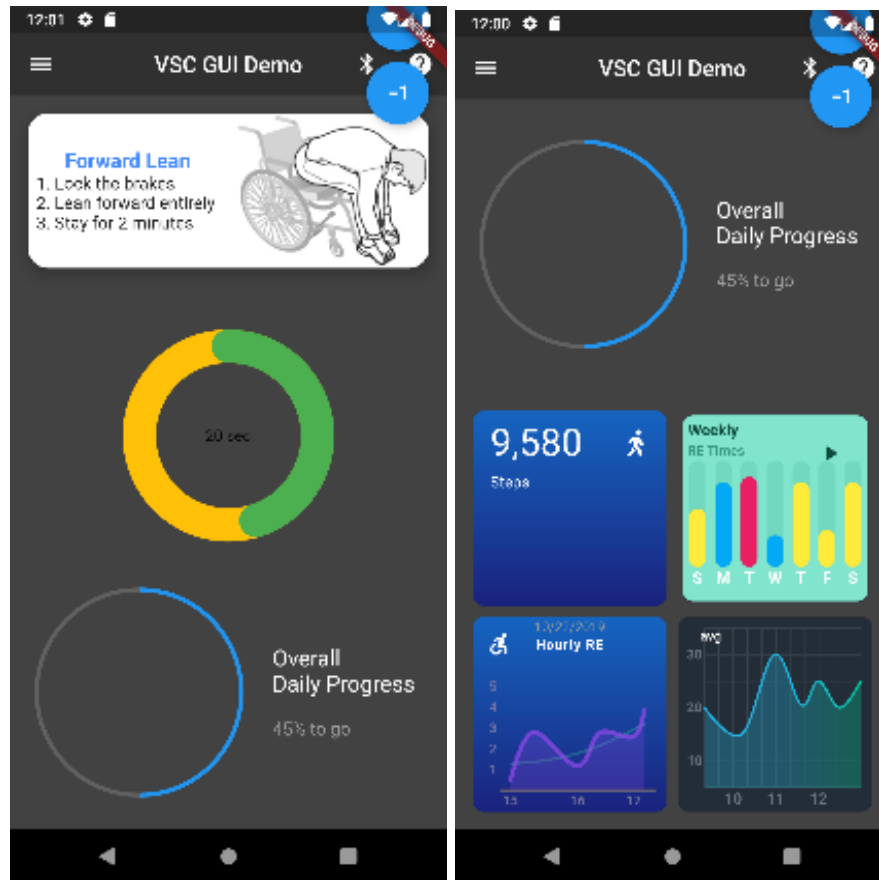


Figure. 16 (Final version) MW-VC Android app

- **Significant Results:**

Throughout the research period, the software application was continuously updated based on user and clinician input. **Flutter**, which is an open-source mobile application development framework created by Google was used for software development. The upgrade of the GUI provided the user to easily track progress and see daily & weekly activity history for the repositioning exercises.

Successful BLE connection to a smartphone with data acquisition through notification was established. The mobile application was examined for long term reliability. During the usability trial, the application uploaded daily usage to the cloud including application start time, menu exploration, error messages, and pressure relief reminders. However, some participants forgot to charge the system every day and the application was not able to acquire and upload the sensor data.

Work related to: Major task 4
Accomplishment #4:

- **Specific Objectives:**
 - Create CAD and CAM files from mechanical and electronic components
 - Create and refine prototype from mechanical and electronic components
- **Major Activities:**
 - 1) During the first quarter, a low-cost system based upon quantum tunneling composite (QTC) sensors was designed, calibrated, and tested. However, it was observed that, under the expected loading conditions, QTCs exhibit a quasi-binary, rather than continuous, response, and therefore would be better used as switches rather than sensors for pressure mapping. The extent of the hysteresis demonstrated may also affect the QTCs' viability for the MW-VC. The continuous exertion of pressure on the seat pan, would keep the QTC pills in a compressed state unless there were additional structural components added such as springs or stands. This continually compressed state would cause the pressure tracking to be offset for the next scheduled pressure relief action. Thus, the Manual Seating Coach electronics design was revised to use custom printed circuit boards (PCBs) for the collection, storage, and transmission of force data. PCBs were developed for the power supply, amplifier board, and for connecting with a Texas Instruments Wireless Sensor Tag board.
 - 2) The circuit took inputs from load sensors incorporated into the seating system, amplified the signals, and converted them for digital processing. The amplifier board used four INA122 instrumentation amplifiers and an ADS130E08 analog front-end (AFE) from Texas Instruments, which included a 12-bit ADC for converting the voltage data to a digital format. A circuit using four Lithium-ion battery cells with a voltage regulator was also designed, allowing for light-weight battery powering of the amplifier board. The AFE on the amplifier board then used the Sensor Tag to transmit the data in digital format via Bluetooth to the Android phone application for further processing. The schematics and printed circuit board (PCB) layout was completed using Altium Designer for both the amplifier board. During the second quarter, custom printed circuit boards (PCBs) for the collection, storage and transmission of force data were fabricated. PCBs were also developed for the power supply, amplifier board, and for connecting with a Texas Instruments Wireless Sensor Tag board as shown in figures below:



Figure 17. Amplifier board with Sensor Tag & Debugger

- 3) A rechargeable power supply from Morphie was selected to provide battery power to the PCBs. Strain gauge validation was done for hysteresis/linearity. Inventory of sensors were created (Light, gyro, accelerometer). Firmware for the Wireless Sensor Tag was developed using the Texas Instruments TI-RTOS and BLE SDKs to facilitate the collection and transmission of sensor data from the Sensor Tag and the amplifier board. TI-RTOS is a real-time operating system kernel used to handle precise scheduling of processes on-board the Sensor Tag. An API for interfacing the analog

front-end (ADS130E08IPAGR, chip from Texas Instruments) with the Sensor Tag via serial communication was also developed as part of the firmware.

- 4) In the following quarters, the electronics boards were updated. The decision to change from the Texas Instruments Sensor Tag boards previously used was based on reliability and barriers to further development. Additionally, the Sensor Tag boards proved to have reliability issues with wireless connectivity that would likely impact data collection. The new electronics hardware allows us to capture the same analog signals from our custom-built force sensing instruments in addition to motion and positioning sensor data while connecting via Bluetooth to the phone app. Another improvement over the TI Sensor Tag boards is the increased on-board memory for storing data.

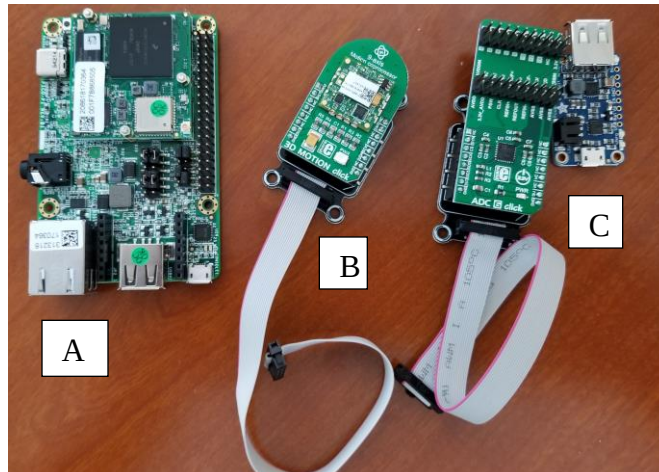


Fig 18. Electronics, A - PICO-PI-IMX7 board; B - one Click 3D Motion sensor; C - one Click ADC6 multi-signal board

The electronics for MWVC now utilized hardware based around the Android Things PICO-PI-IMX7

board from TechNexion. The peripheral sensors are connected via two secondary boards from Mikroelektronika, one Click ADC6 multi-signal board and one Click 3D Motion sensor featuring a 9 DOF IMU and integrated motion coprocessor. The Android Things boards allow us to focus and accelerate development by eliminating the need for fabricating and assembling additional printed circuit boards.

- 5) In the following year, based on user feedback from the first few participants, some wires were rerouted to ensure they are not pulled as the wheelchair is loaded/unloaded from a vehicle. It was observed that it was difficult to find appropriate location for the electronic housing while installing on one of the recruited participants' wheelchair due to additional accessories under the seat such as handbags or brackets for the wheelchair lifts. Moreover, during the 5-day usability study, one participant reported that the electronic box was falling from the seat due to the loss of adhesiveness of the Velcro tape. Therefore, a new single board computer (Udoo Neo, made by Seco Inc.) was used to enable on board storage of load cell data during the trial, which could be subsequently processed to further improve our seated posture algorithms and conduct post hoc analysis of unexpected results. The new SBC also has the computing power to offload substantial portions of the algorithm from the phone, which improved smartphone battery life, and kept the android operating system from stopping the Virtual Coach as a resource intensive process. The housing of the electronics was also reduced to accommodate the smaller sized single board computer (UDOO Neo), due to limited space under the seat and larger vibration from active daily activities. UDOO Neo provides internal acceleration and inertial measurement unit (IMU).
- 6) This redesigned housing (3.25"x5"), shown in Figure 19A is 2 inches less in length and 0.25 inches in width. Mounting screw holes were added to the bottom of the box in order to mount on the seat panel. Additionally, access cover was added to the bottom of the box for easy replacement of the batteries. As shown in Figure 19, the electronic boards from the top are load cell amplifiers, single

board computer, charging circuit, and batteries. Five amplifier PCBs were fabricated. The PCBs were tested to calibrate the no-load output voltage as 1.65V while supplying 3.3V. The gain resistors on the PCBs was calibrated using different weights from 1-50 lbs. ensuring that the dynamic range of the output voltages was within the 1.2V. A 3D printed housing was fabricated to hold the amplifier, battery, battery charging PCB, and the single board computer.

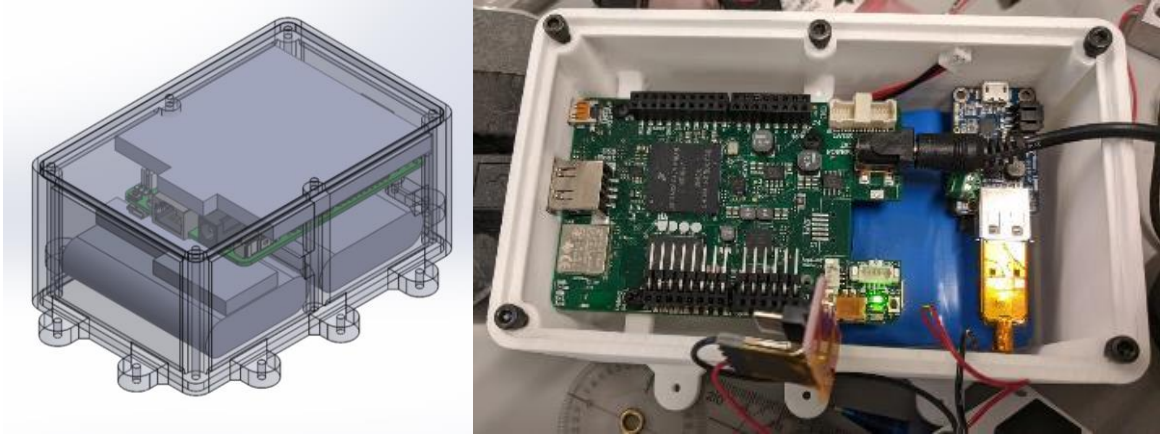


Figure 19. Electronics housing, A – CAD design of electronics housing; B – 3D printed housing for the electronics

- 7) **Mechanical updates:** The force-sensing load cells are a low-cost alternative to manually applied strain gauges used in previous design work. They are 1000 Ω strain gauge sensors applied in a half-bridge configuration, allowing for bi-directional detection of forces. They are arranged at four points on the seating system to detect forces in the vertical direction, allowing for the calculation of center of pressure in both the lateral and the fore/aft directions. Additionally, dynamic forces acting upon the seat in bouts of activity (e.g. wheel propulsion, pressure relieving exercises, etc.) can also be detected. Below are the mechanical models of the main assembly and spider assembly:

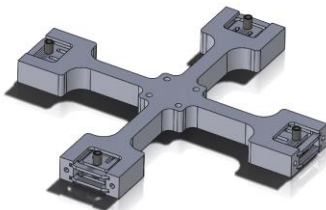


Figure 20. Spider ASM Iso



Figure 21. Main ASM Iso Bottom Right



Figure 22. Main ASM Front



Figure 23. Main ASM Iso Top Right Seat Explode



Figure 24. Main ASM Iso Top Right

- 8) The mechanical design consists of a pilon, a “spider”, 8 half-bridge force sensors, a carbon fiber seat pan, and an electronics housing. The pilon consists of machined aluminum and connects the spider to the frame crossbar. The spider is a machined piece of aluminum that holds the 8 half-bridge in their proper configuration. The spider has 4 legs, with each leg having two grooves to accept two force sensors. An end cap on each leg holds the sensor in place. The grooves are specifically designed to allow the sensors to float lateral for a small distance, which helps prevent the introduction of bending caused by internal loading due to small misalignment of the final assembly. The half-bridge force sensors are the major change from the preliminary version on of the device.
- 9) These sensors are OEM components used in the bathroom scale industry and are available in bulk for around \$0.40 apiece. They consist of a stamped metal tab with a two-resistor strain gage bonded to it and leads soldered to the gage. An additional layer of RTV covers the gage, providing protection for the gage and strain relief for the leads. The design stacks two of these force sensors back-to-back on each leg, coupled with hardware, and fixed to the carbon fiber seat pan. The sensors on each leg are wired to form a full strain gage bridge, which mechanically amplifies the signal and, helps reject signal disturbances caused by temperature fluctuation and EMF. The OEM sensor replaces high-end two-resistor strain gages that cost around \$12 each and, required much labor time to apply and solder. This reduces sensor cost from around \$48 to \$3.20, making the device more viable for larger clinical trials or commercial translation. The carbon fiber seat pan is lightweight and stiff, allow portions of it to be cantilevered, as well as behave mathematical modeling-wise as a ridged object. A solid model of the device shown in figure 23.
- 10) There were no significant changes in the overall mechanical design throughout the project period. As shown in figure. 25, the pilon consists of machined aluminum and connects the spider to the frame crossbar. However, during the usability study, we noticed that when the spider was attached to the frame crossbar, it increased the floor to seat height. Therefore, we redesigned (figure. 25) and fabricated a new crossbar, mounting clamps, carbon fiber seat pan, and spider to resolve this issue. Additionally, this helped to compensate for the differences in the location of the crossbar in manual wheelchairs. A solid model of the device assembly is shown in figure 26.

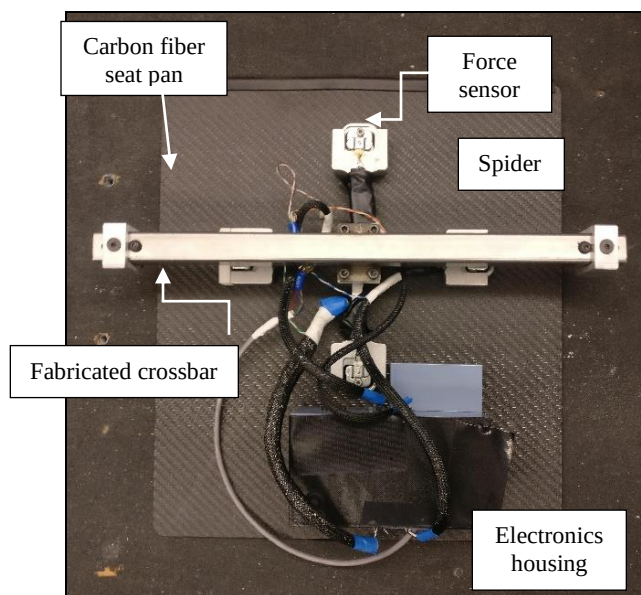


Figure 25. Fabricated Seat Pan

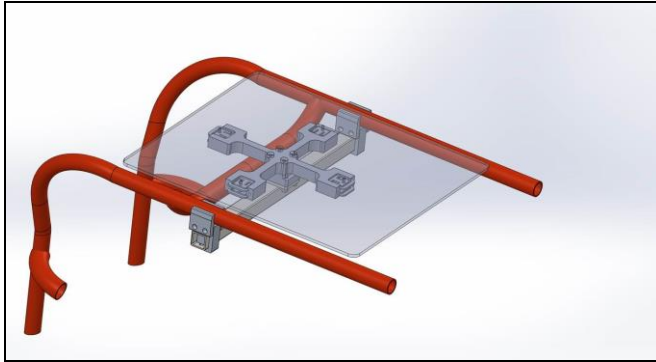


Figure 26. Standard instrumentation configuration

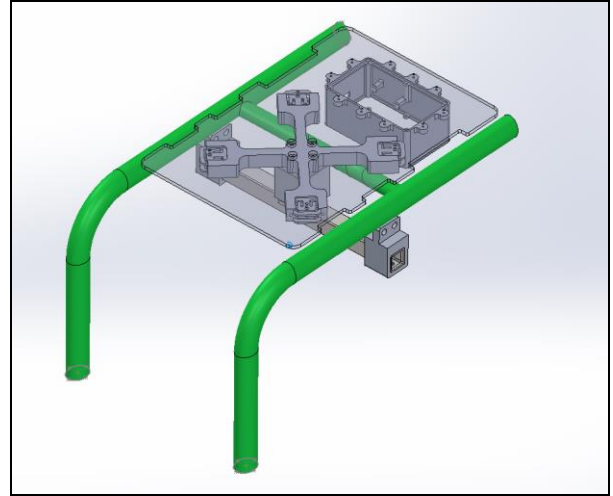


Figure 27: CAD model of instrumentation package with cross configuration for narrow wheelchair frames.

- 11) Since every individual's manual wheelchair is different, there is a need to customize to ensure correct fitting. To fit the load cell crossbar and the controller device to various seat pan size and wheelchair frame structures, we developed three different designs. As shown in Figure 28, the middle one was close to the original design with one load cell at each direction of the seat and placed close to the edge of the seat pan. The left one shows a similar design with the larger seat pan and the crossbar was attached to a clamp rod that had clamps at two ends to hold the MWVC in position. Two participants were using a small seat, which the original design was not able to fit. The right design in Fig 27, 28 shows the configuration for the narrow-sized seat. The load cell crossbar was placed with 45-degree rotation as an 'X' so that there were two load cells at each side of the seat pan. This was accounted for in the data collection process to ensure consistency between the different configurations (See equation 1, 2). We installed a rubber strip at the front end of the seat to protect from scratching participants' cushion or skin. The controller was placed based on the wheelchair frame structures and the placement of the load cell crossbar. For example, the left design in Fig 28 shows that the controller was placed at the front side of the seat. The controllers on the other two designs were placed at the rear end of the seat.

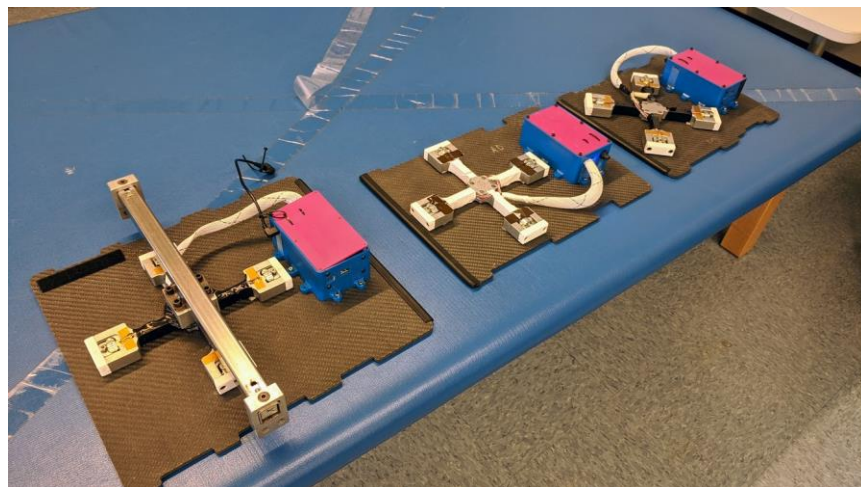


Figure 28. Load cell crossbar and controller arrangement for different seat pan sizes and wheelchair frame structures.

- 12) Equation 1 shows the computation for the original setup (left and middle design of Fig 28). The center of pressure at the x-axis was determined by the force applied on the right and left load cells and the distance of two load cells.

$$\begin{bmatrix} x_c \\ y_c \end{bmatrix} = \begin{bmatrix} \frac{\frac{d}{2}F_{right} - \frac{d}{2}F_{left}}{F_{right} + F_{left}} \\ \frac{\frac{d}{2}F_{front} - \frac{d}{2}F_{back}}{F_{front} + F_{back}} \end{bmatrix} \quad (1)$$

Equation 2 was used to compute the center of pressure for the X configuration. The center of pressure at the x-axis was determined by all four forces measured at four corners of the seat. The distance was reduced due to the 45-degree rotation.

$$\begin{bmatrix} x_c \\ y_c \end{bmatrix} = \begin{bmatrix} \frac{\frac{d\sqrt{2}}{4}F_{front-right} + \frac{d\sqrt{2}}{4}F_{back-right} - \frac{d\sqrt{2}}{4}F_{front-left} - \frac{d\sqrt{2}}{4}F_{back-left}}{F_{front-right} + F_{front-left} + F_{back-right} + F_{back-left}} \\ \frac{\frac{d\sqrt{2}}{4}F_{front-right} + \frac{d\sqrt{2}}{4}F_{front-left} - \frac{d\sqrt{2}}{4}F_{back-right} - \frac{d\sqrt{2}}{4}F_{back-left}}{F_{front-right} + F_{front-left} + F_{back-right} + F_{back-left}} \end{bmatrix} \quad (2)$$

The two equations were implemented in the controller for computing center of pressure. Besides, because the center of load cell crossbar was not often aligned to the center of the seat due to wheelchair frame structures, a small amount of offset in the y-axis was applied to adapt the difference between wheelchair frame designs.

- **Significant results:**

The electronics and their packaging were reduced to a 1/4th of the size of the previous prototypes and several considerations for wire management and functionality were added. Additive manufacturing was leveraged to create a custom enclosure for the electronics. All components were manufactured using CNC technologies (milling, waterjet, additive manufacturing), along with custom work holding fixtures, allowing for quick and labor efficient means of producing multiple iteration during the project. Figure 29 shows the assembled device on different manual wheelchairs. Multiple Spiders were manufactured along with a customized seat pans made from carbon fiber.

We have gained the ability to store significant amounts of data on board for post-trial analysis. Software representation of loads corresponds with measured voltages and forces applied. Android Things boards eliminated need for in-house fabrication of custom PCBs, Unused/unnecessary sensors were removed from hardware to improve battery life, battery charging circuit and chargers added to improve device deployment time and hardware reliability issues with wireless Bluetooth connection were resolved.



Figure 29. Device assembly on a manual wheelchair

Work related to: Major task 5

Accomplishment #5: Conduct usability testing for Specific Aims 1-3.

- **Specific Objectives:**

- Recruit and enroll participants
- Conduct focus group with MW-VC
- Complete 5-days in home trial

- **Major Activities:**

- 1) IRB approved flyer for this study was distributed at Wheelchair events, SCI support groups, etc. to potential subjects according to the procedures established in the IRB approved registry protocols. Pitt+Me was used for recruitment via approved postings to their website. The advertisement was posted on the HERL website (www.herl.pitt.edu) and Facebook page and shared through personal and professional contacts. All the recruitment materials instructed potential subjects to contact a clinical coordinator for additional information. When interested participants called, a brief phone screening was conducted, in order to assist in determining eligibility prior to scheduling an appointment.
- 2) All subjects were considered enrolled in the study once they signed the informed consent but prior to the initiation of study procedures. Once consent had been obtained it was verified that they met inclusion/exclusion criteria. They were asked about manual wheelchair users' pressure relief education and compliance. A member of the study team provided a demonstration of the Manual Wheelchair Virtual Coach. Through a series of questions participants were encouraged to share and discuss their impressions and suggestions. Measurements of eligible and interested participant's wheelchairs were recorded for seat pan fabrication purposes for the 5-day in home trial.
- 3) Twenty participants (twelve males, age: 23-75) consisting of manual wheelchair users (MWU) and clinicians/caregivers participated in the focus group. We received several useful feedbacks which was incorporated into the design. Key issues were addressed before initiating the 5-day in home trial. We enrolled **five** additional MWUs to test out the updated system. The study involved 2-3 visits; the initial visit where the individual's wheelchair measurements were taken to fabricate a customized seat pan; second visit involved fitting the device and explaining how to use the phone application; and the third visit to uninstall the system after 5 days and for the MWU to share their thoughts and opinions on using the coaching system. The usability study established a basic framework for further improvement in the upcoming pilot study.
- 4) The 5-days in home trial was completed by five MWUs (5 males, average age: 41 years, average weight: 168 lbs.). Key issues were addressed and remedied before the pilot study. The inclusion/exclusion criteria considered were: Above 18 years of age, spinal cord injury, used a manual wheelchair with rigid frame at least 40 hours per week, must be able to independently perform a weight-shift or to reposition themselves for pressure relief, free from pressure injuries, any back, pelvic, or thigh pain that would limit sitting tolerance.

- **Significant results:**

Twenty participants consisting of MWU and clinicians were recruited for the study. Of the ten MWUs, seven reported that they developed pressure ulcers even though they received pressure relief

education during their rehabilitation. The clinicians talked about their background and were asked questions about pressure ulcer prevention training.

A member of the study team provided a live demonstration of the MW-VC. Through a series of questions, participants were encouraged to share and discuss their impressions and suggestions on the following topics: Innovation, Function, Usability, Training, Appeal, Environment, Serviceability, and Physical Specifications. Overall, participants rated the MWVSC highly for innovation, usefulness, and compactness. Some key findings were: (1) The system should be a standard part of acute rehabilitation after SCI for maximum effectiveness of instilling good pressure relief behaviors; (2) Methods for alerting the user — visual messages, tones, vibrations — must be customizable; (3) Visual feedback should not be the only mode available for conveying when the user is in an effective pressure relief position, as the phone may not be in the line of sight in that position; (4) The carbon fiber seat pan looks good. Hardware is compact. However, visible wires and sharp edges should be avoided; (5) Most users would expect to charge the chair every night, but extra capacity should be built in for when they forget. Low system battery should be signaled on the phone. Recharging the system must be easy for those with limited hand dexterity. A removable battery may be helpful; (6) Some users may carry heavy items on their laps, so the system must recognize this condition; (7) Users should be alerted to improper sitting posture — for example a persistent lean to one side or the other; (8) The smartphone application is easy to use and train others as well. The app should not feature too much text and clicking and should also have an option for the user to send comments/disagreements; (9) Have a switch in the wheelchair that is easily accessible and would allow the user to dismiss alerts during a meeting or activity; (10) A future option should be having the app support smart watch integration.

During the 5-days in home trial, it was reported that there were occasional Bluetooth disconnections during the day which resulted in missing several repositioning exercise reminders. The reminder was designed as initiated by the under-seat device. The recording software and Android application were modified to detect the connection loss and correct this error; the software releases the Bluetooth serial port after sending data to the Android application and checks the availability before sending data. Moreover, the Android application was updated to include backup timers for reminders if connection is lost. The connection was tested for the stability, re-connectivity, and connection distance. The system was able to connect and reconnect 10 times. The system was tested for 40 hours running without crash. The connection distance affected the signal strength. Within one foot, the signal strength was -38dbm to -42dbm. At 41 feet, the signal strength dropped to -58dbm. However, the Android application was still able to connect to the recording software and read sensor data.

Work related to: Major task 6

Accomplishment #6: Conduct a Pilot Clinical Trial.

- **Specific Objectives:**
 - Recruit and enroll participants
 - Conduct 4 weeks pilot study
 - Determine modifications to protocol that are needed to implement larger scale study
- **Major Activities:**
 - 1) The key issues identified during the 5 days usability study corrected the connection error and the connectivity test shows that the system was able to record all activities and stay connected to the Android device within an indoor living environment. All study steps, data collection and database requirements have been coordinated. Research participants from the usability study

have expressed interest to participate in the 4 weeks pilot study. Participants were recruited from research registries and professional contacts.

- 2) The study involved 3 visits; During the initial visit, basic demographic information such as age, gender, level of education and information about subject's wheelchair use was obtained along with Craig Handicap Assessment and Reporting Technique Scale (CHART). We also measured the wheelchair dimensions to create a CAD drawing for cutting carbon fiber board and manufacturing support parts. As the seat sizes are different from person to person, the arrangement of each load cell crossbar and the controller was customized to the size limit of the chair. Second visit involved fitting the device and explaining how to use the phone application; and the third visit to uninstall the system at the end of study period and for the MWU to share their thoughts and opinions on using the coaching system. The total duration of the study involved 4 weeks (1 week of baseline monitoring, 2 weeks of coaching intervention, 1 week of monitoring for changed behavior). Ecological momentary assessment technique was used through the MW-VC phone app to collect the Tool for Assessing Wheelchair discomfort (TAWC) after every three-days. All the data throughout the study was automatically uploaded to a secure cloud-based storage site. We are currently wrapping up with the study as we continue to receive useful feedback from our research participants.

- **Significant results:**

Ten participants (5 females, 5 males) were enrolled in the *four-week pilot study*, out of which 5 individuals have completed the study to date. We observed few participants had dexterity challenges which made it difficult to reach the device in order to charge the MW-VC. An innovative solution was identified to solve this problem; a magnetic end was incorporated in the charging cable.

To comply with the university policies regarding research, HERL had paused any research involving face-to-face interaction due to the COVID-19 situation. Currently we are working to restart research so that the remaining 5 participants can also complete the study and their respective MW-VC can be retrieved for further analysis. The results of the pilot study will also allow us to make changes to improve the design of a future study.

Work related to: Major task 7

Accomplishment #7: Data Analysis

- **Specific Objectives:**
 - **Monitor data collection rates and data quality**
- **Major Activities:**

- 1) Signal processing (Figure.30): During the **5 days usability study**, we found an extremely low-frequency drifting in the analog output signals possibly due to surrounding noises. The outputs start oscillating about every 20 seconds. We applied the Kalman filter for removing this low-frequency oscillation but also kept a quick response for the weight shifting. After applying Kalman filter, the noise was eliminated, and it still provides fast response to the weight changes. In addition, it also helps to improve the shifting from the increased temperature. Although we have tried to optimize the Kalman parameters for the system, we still record the original sensor data for further improvement if we find problems in the subject testing.

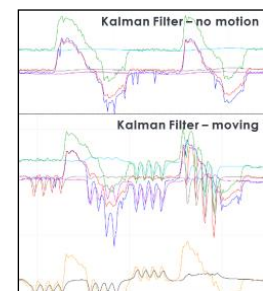


Figure. 30 Kalman Filtered load cell readings

- 2) The electronics were modified to include on-board storage for system messages and raw data. The test shows that it took about 2GB for one day data. Figure. 31 shows the CoP moving trajectory and acceleration of one participant. The trajectory helps to see user's moving habit and trend. For example, this participant moved more on the right than the left. We confirmed this during post-trial interview where the participant reported that he has concerns about bump on the left bottom skin and tended to lean to the right more in order to relieve the sitting pressure on the left. In addition, the acceleration data showed the activity on the chair. For example, there is no acceleration changes after 20:00 which might suggest the user was outside the chair.

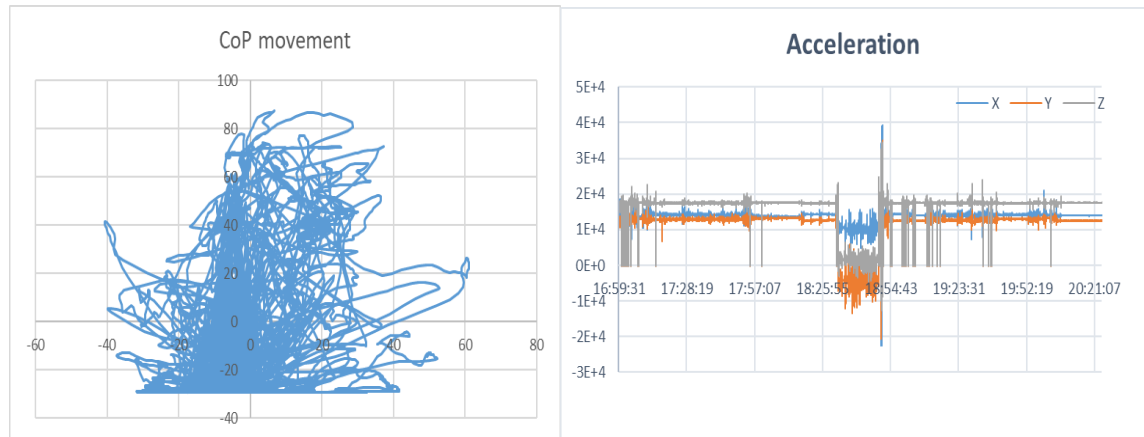


Figure 31. CoP moving trajectory and acceleration

- 3) For the pressure relief data (figure 32), the single board computer recorded when and how long the user is inside the effective pressure relieving areas. The chart shows the duration from 17:00-20:00. It shows the user responded to the 30-minute reminder at 19:00 and 19:34. However, the user was able to remain in the position for 19 seconds most.

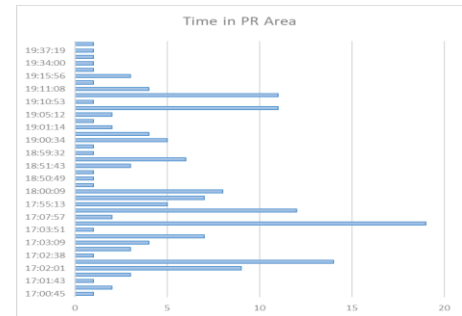


Figure 32. Pressure relief data

- 4) Figure. 33 shows how much time the participant stays in the effective pressure relieving areas. The participants stayed more time in pressure relieving areas between 17:00-18:00 and 19:00-20:00. The frequency is shown in orange color. In combination of the acceleration data, there are significant movement between 18:00 to 19:00 which might be indication of the participant was in transportation or moving. This explained the reduced pressure relieving exercises between 18:00 to 19:00. Therefore, the electronics not only shows the pressure relieving from CoP movements but also the daily activities from the inertia measurement unit which facilitate to explain and reasoning the daily usage on the wheelchair.

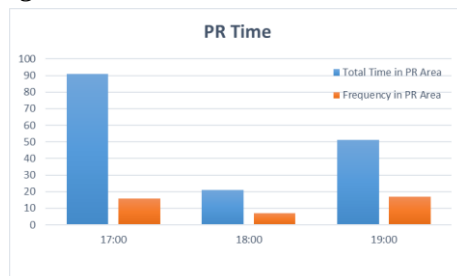


Figure 33. Pressure relief time

- 5) In the **4-week pilot study**, the Android smartphone application uploaded the pressure-relieving activities to the Google Firebase cloud database for researchers to monitor the status of the system. Due to the limitation of daily writes (50k/day), the update rate was reduced but it may be increased for future upgrade of Firebase data plan.

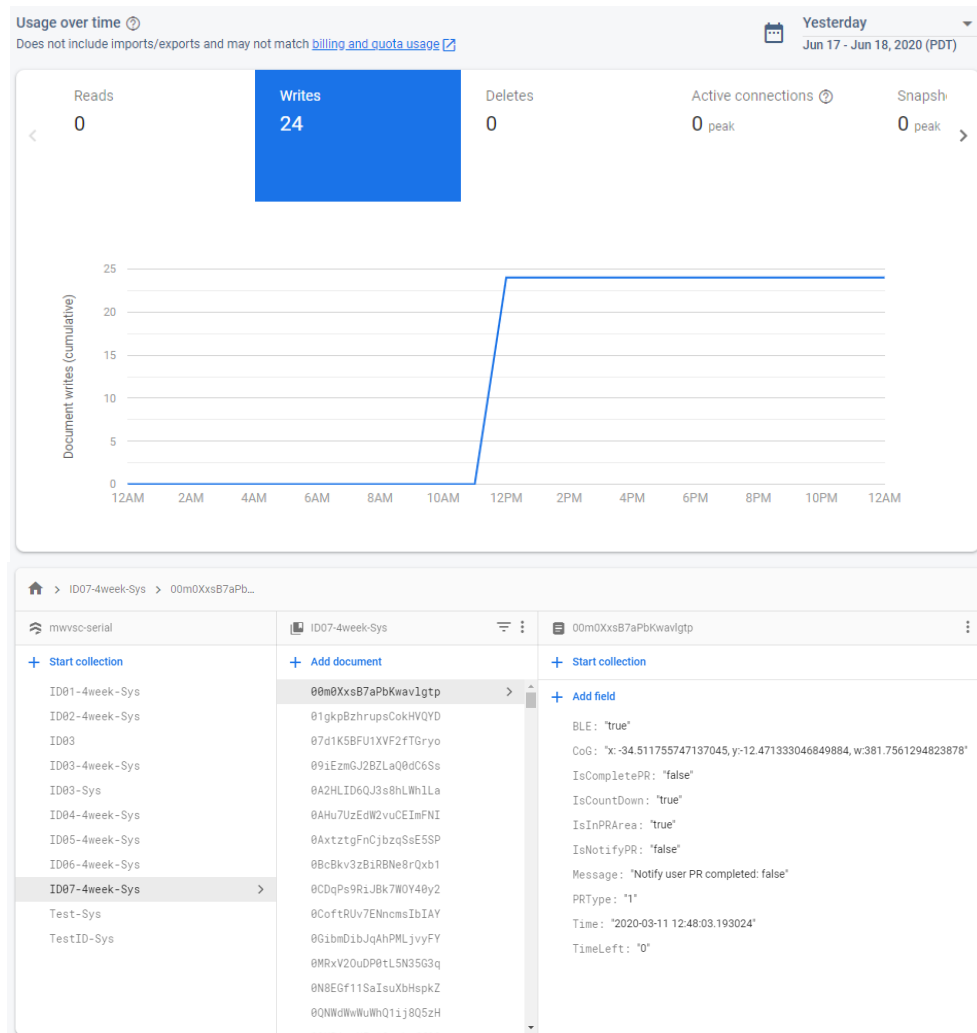


Figure 34 Firebase database for the remote monitoring of the system status

- 6) After collecting data from the 4-week pilot study, Matlab programs were developed to analyze the raw data. The file size of one day was about 1-2 GB. The raw data included the date and time, load cell analog to digital converter (ADC), Kalman filtered ADC, computed center of pressure, weight, acceleration, angular velocity for gyroscope, the magnetic force from magnetometer, and system status including Bluetooth connection and status, pressure-relieving types and detection results. Figure 35 shows the data from 5 days in the 4-week trial. It shows the weight and center of pressure changes each day, colored in different colors. Some data were missing due to insufficient battery. The center of pressure shows the tendency of the user's daily movement.

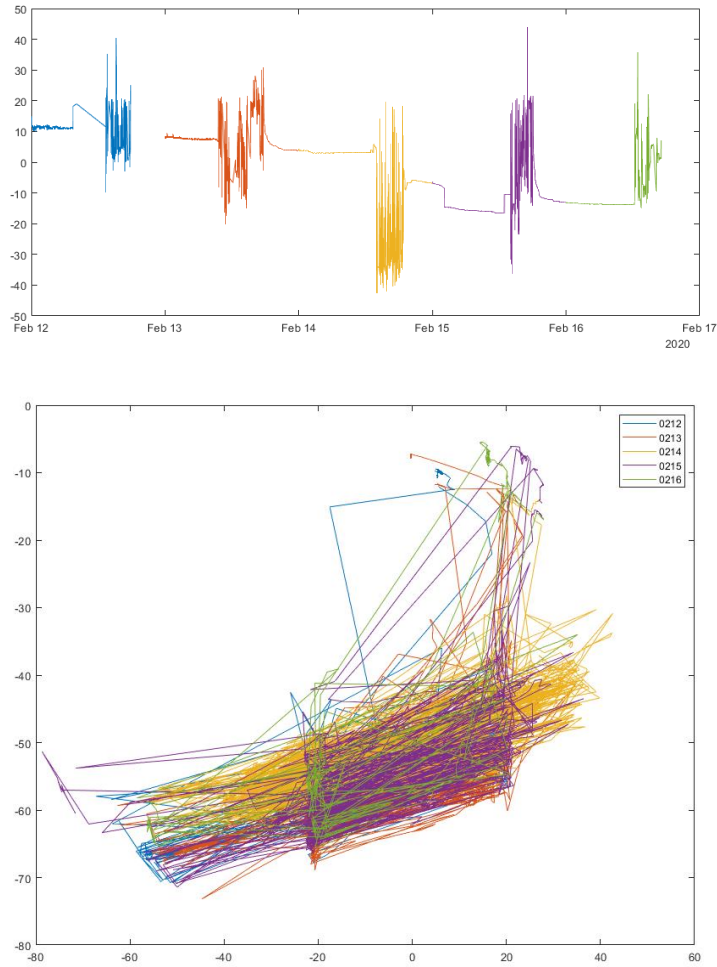


Figure 35. Data collected from the 4-week pilot study

- 7) Figure 36 shows the comparison between the weight and the acceleration measured from the load cells and accelerometer in the controller, respectively. When the user transferred in and out of the chair, both showed significant changes. However, there are sometimes that the acceleration did not change but the weight was changed. It could be the user was in the chair

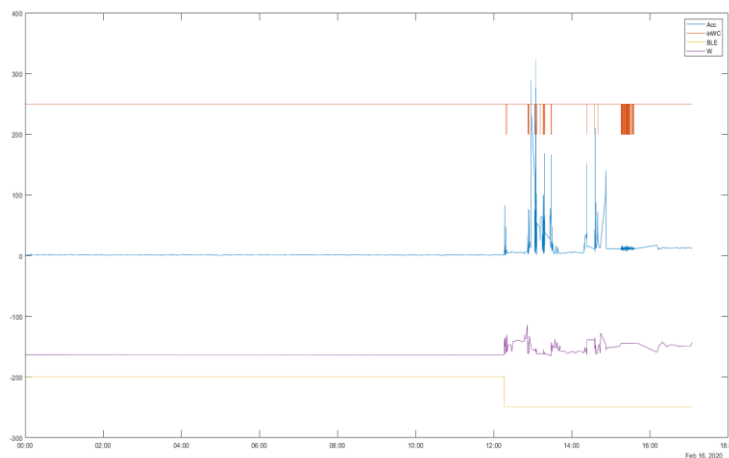


**Figure 36.
Comparison
between
acceleration and
the weight**

sitting statically. The opposite situation is that the weight was not changed but the acceleration changed. This could be the user was not sitting in the wheelchair but on transportation. The data could provide other daily activities other than pressure relieving.

- 8) Figure 37 shows the comparison of time in the wheelchair (orange) and the total time of daily recording (blue) from one participant's 4-week data. One participant spent about 50000-60000 seconds daily on average in the wheelchair. However, if the participants forgot to charge the battery, the total time was dropped significantly. On some days, although the total recording time was high, the time in the chair was low, e.g., Feb 18.

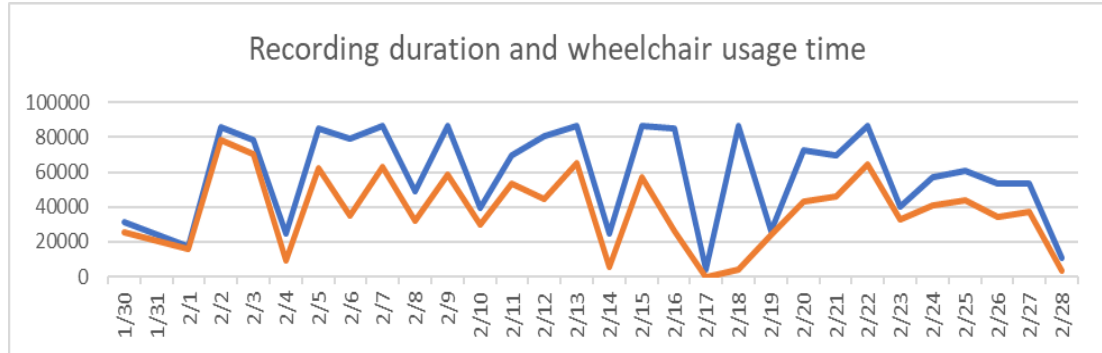


Figure 37. Comparison of time in the wheelchair (orange) and the total time of daily recording (blue) from one participant's 4-week data

- 9) Figure 38 shows the pressure-relieving behavior from two participants in the 4-week trials. One participant only performed pressure relieving about once every few days. The other one performed almost every day at the beginning of the trial but reduced forward lean after 2-weeks after the study started.

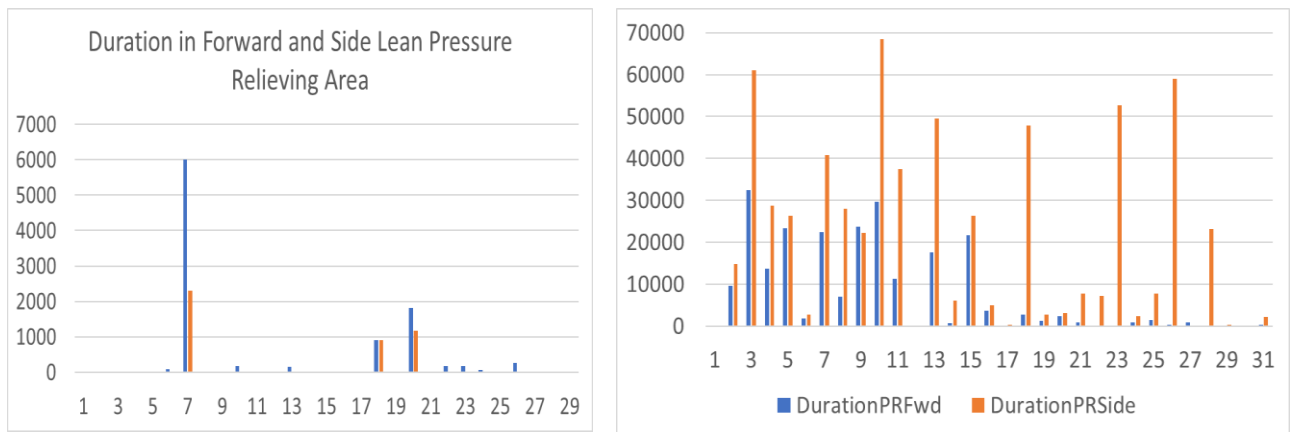


Figure 38. Comparison of the pressure-relieving behaviors (blue: forward lean, orange: side lean) from two participants in the 4-week trials

- **What opportunities for training and professional development has the project provided?**

In addition to supporting full time engineers and staff, this project has provided learning opportunities to the team. Members of the team – especially Dr. Chung – undertook significant self-study to implement a new low-cost, high capability, X86 II single board computer that can be additionally utilized in other projects.

- **How were the results disseminated to communities of interest?**

Through subject recruitment activities and personal experience with the system by research participants, we have increased awareness of the constant need for pressure injury prevention, as well as our unique solution for increasing the frequency and effectiveness of pressure reliefs. Presentations at funding competitions have exposed a wider community to the importance of pressure injury prevention.

- **What do you plan to do during the next reporting period to accomplish the goals?**

Nothing to report

4. IMPACT:

- **What was the impact on the development of the principal discipline(s) of the project?**

The in home trial of the Manual Wheelchair Virtual Coach demonstrated that it is possible to remotely monitor when manual wheelchair users are doing pressure reliefs, give them real-time feedback on whether their attempted pressure reliefs are likely effective, and gather more detailed information on their changes in seated position all while the user is performing his or her usual activities in the community.

- **What was the impact on other disciplines?**

Nothing to Report.

- **What was the impact on technology transfer?**

In July 2019 we filed an international patent application to protect intellectual property from this project to preserve value for a future independent company or licensing deal. We received a copy of the Written Opinion (WO), International Search Report (ISR) and the cited prior art references from the United States Patent and Trademark office (USPTO) acting as the International Searching Authority (ISA) for this PCT application. The Written Opinion is an initial preliminary non-binding opinion of the ISA about novelty, inventive step (no obviousness) and industrial applicability of the invention covered by the PCT application. No objections to novelty, inventive step or to industrial applicability were raised by the ISA based on the prior art documents found during the search. Early this year (2020), notice of Publication was issued by the International Bureau. This application was published on January 16, 2020 under the international publication number: WO 2020/014430

- **What was the impact on society beyond science and technology?**

The MW-VC system, in its current form, provides a tool for both clinicians and manual wheelchair users to obtain objective data about the frequency and likely effectiveness of pressure relief maneuvers. By being lower cost than the current objective standard of pressure mapping, and with the ability to be used by any manual wheelchair user in his or her daily life, our current system already has the potential to improve pressure relief education and user behavior – leading to a reduction in pressure injuries.

5. CHANGES/PROBLEMS:

- **Changes in approach and reasons for change**

No significant changes were made to the overall objective and approach.

Originally, we intended to enroll ten subjects simultaneously for the five-day in-home trial. Since the purpose of this part of the study was to identify points of failure in the system and suggestions for improved ease-of-use, we chose instead to enroll five participants sequentially, so that we would have more iterative opportunities to improve the system, while making efficient use of project resources and study subject time. Though the pilot study was conducted simultaneously with multiple participants, staggered start dates gave us the opportunity to continue improving the user experience with feedback from the first users.

- **Actual or anticipated problems or delays and actions or plans to resolve them**

Both hardware and software required more time for development than initially allotted due to changes in personnel, necessary changes in microcontroller platform, and bugs in software drivers. We were also forced to halt in person research activities due to COVID-19. The last few months allowed us to take time to thoroughly analyze data from the first set of participants and implement improvements that should produce better data for the remaining research participants in the study.

- **Changes that had a significant impact on expenditures**

No significant changes in expenditures.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Significant changes in use or care of human subjects:

No significant changes

6. PRODUCTS:

- **Publications, conference papers, and presentations**

A poster was also submitted for display during the 2020 Research Week held by the Department of Veterans Affairs Pittsburgh Healthcare System — which was held remotely.

- Sundaram, S. A., Grindle, G., Gebrosky, B., Brown, J., Cooper, R. M., & Cooper, R. A., (2018). Identification of Pressure Relief Maneuvers Using Changes in Center of Pressure. Abstract published in proceedings of the RESNA/NCART 2018, Arlington, VA.
- Thanyamongkhonsawat, K., Sundaram, S. A., (2018). Characterizing Quantum Tunneling Composite for Use in the Manual Wheelchair Virtual Seating Coach. Paper published in proceedings of the RESNA/NCART 2018, Arlington, VA.
- S. A. Sundaram, G. Grindle, B. Gebrosky, J. Brown, A. Kelleher, R. Cooper, C. Chung, R. A. Cooper. (2020 Under preparation) Identification of Pressure Relief Maneuvers Using Changes in Center of Pressure

Journal publications

Manuscripts on the cluster analysis of pressure relief maneuvers and data obtained in the portion of the Pilot study conducted so far will be submitted for journal publication in July/August 2020.

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers and presentations

Nothing to report

Website(s) or other Internet site(s)

Nothing to report

Technologies or techniques

Nothing to report

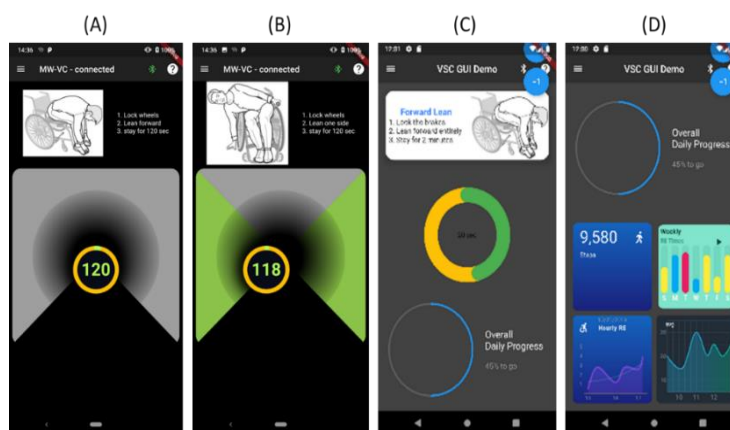
- **Inventions, patent applications, and/or licenses**

WHEELCHAIR PRESSURE ULCER RISK MANAGEMENT COACHING SYSTEM AND METHODOLOGY- PCT International application No: PCT/US2019/041327 (Filed July 2019). The international bureau has published this application on 16 Jan 2020 under No. WO 2020/014430.

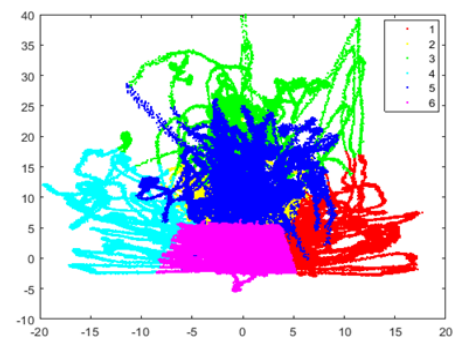
- **Other Products**



Figure. 39 Functional and user tested prototype, including mechanical hardware, electronics, imbedded software, android applications, and online database.



Features of MW-VC Phone Application



Cluster Analysis Showing Different Pressure Relief

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: *Rory A Cooper*
Project Role: *PI*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1.2 Cal months (10% effort)*
Contribution to Project: *Dr. Cooper has overseen all aspects of the research protocol.*

Name: *Garrett Grindle*
Project Role: *Research Scientist and Engineer*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1.2 Cal months (10% effort)*
Contribution to Project: *Dr. Grindle was involved in the design, prototype and calibration of MW-VC.*

Name: *Chengshiu Chung*
Project Role: *Postdoctoral Fellow*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *2.4 Cal months (20% effort)*
Contribution to Project: *Dr. Chung developed and tested machine learning algorithms, designed and implemented MW-VC application*

Name: *Josh Brown*
Project Role: *Electrical Engineer*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1.2 Cal months (10% effort)*
Contribution to Project: *Mr. Brown contributed to the designed, prototyped and calibrated the MW-VC*

Name: *Benjamin Gebrosky*
Project Role: *Mechanical Engineer*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1.2 Cal months (10% effort)*
Contribution to Project: *Mr. Gebrosky contributed towards hardware installation and wheelchair fitting.*

Name: *Matt Landis*
Project Role: *Electrical & Computer Engineer*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *2.4 Cal months (20% effort)*
Contribution to Project: *Mr. Landis worked on the design and implementation of the Application. Furthermore, he was involved in the design, Prototype and calibration of the MW-VC*

Name: Rosemarie Cooper
 Project Role: Clinician
 Researcher Identifier (e.g. ORCID ID):
 Nearest person month worked: 1.2 Cal months (10% effort)
 Contribution to Project: Mrs. Cooper provided overall clinical guidance for the project

Name: Andrea Sundaram
 Project Role: Graduate student researcher
 Researcher Identifier (e.g. ORCID ID):
 Nearest person month worked: 6 Cal months (50% effort)
 Contribution to Project: Mr. Sundaram has performed work in the development and Testing of machine learning algorithms and implementation of the MW-VC application. He has also worked to coordinate the project and promote it to outside groups.

Name: Nikitha Deepak
 Project Role: Research Coordinator
 Researcher Identifier (e.g. ORCID ID):
 Nearest person month worked: 1.2 Cal months (10% effort)
 Contribution to Project: Ms. Deepak was involved in IRB submissions, testing and reporting of progress.

Name: Stacy Eckstein
 Project Role: Clinical Coordinator
 Researcher Identifier (e.g. ORCID ID):
 Nearest person month worked: 1.2 Cal months (10% effort)
 Contribution to Project: Mrs. Eckstein was involved in obtaining regulatory Approvals and communications for local IRB and DoD.

Name: Paul Trichon
 Project Role: Undergraduate Computer Science intern
 Researcher Identifier (e.g. ORCID ID):
 Nearest person month worked: 1.2 Cal months (10% effort)
 Contribution to Project: Contributed to the development of the smartphone app Machine Learning

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
Nothing to Report
- **What other organizations were involved as partners?**
None

8. SPECIAL REPORTING REQUIREMENTS

Quad chart (See appendix)

9. APPENDICES:

Quad chart
 Abstract
 Paper

Manual Wheelchair Virtual Seating Coach

SC160273

W81XWH-17-1-0620



PI: Rory Cooper

Org: Human Engineering Research Laboratories

Award Amount: \$148,922.00

Study/Product Aim(s)

- Aim 1: To obtain a record of manual wheelchairs (MW) seated center of pressure (CoP) patterns during usage by people with spinal cord injuries (PwSCI) and to relate that to surveys of activity, participation and seating discomfort.
- Aim 2: To determine if virtual coach features of the MW reduce seating discomfort and improve adherence to Clinical Practice Guidelines (CPG).

Approach

Develop a smart phone based coaching system consisting of force sensors to measure the weight distribution on wheelchair's seat and artificial intelligence algorithms to instruct the user on effective pressure relief (PR). Additionally, conduct usability testing and a pilot study of the MW-VC prototype with PwSCI and clinicians.



Figure 1

Figure 1: Prototype interfaced with participant's manual wheelchair

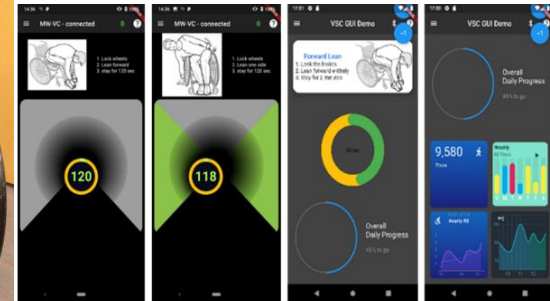


Figure 2

Figure 2: Smartphone application

Timeline and Cost

Activities	Q1	Q2	Q3	Q4
Expert System and Machine Learning Algorithms				
Application Software				
Seating Systems Sensing Package				
Conduct Usability Testing				
Pilot Study				
Prepare Proposal for MW-VC Clinical Trial				
Estimated Budget (\$K)	Project completed			

Updated: 6/24/20

Goals/Milestones

Q1 Goal – Initiate application software/hardware development to include expert system & machine learning algorithm, finalize protocol for usability study

- ✓ Institution approval (IRB, HRPO)
- ✓ Simulate expert learning algorithms in MatLab
- ✓ Test & validate machine learning algorithms using MatLab
- ✓ Complete solid models, drawings, parts-list

Q2 Goal – Design, prototyping, calibration of MW-VC and conduct usability testing

- ✓ Complete working prototype for wheelchairs
- ✓ Usability study completed and design refined

Q3 Goal – Begin pilot trial

- ✓ Protocol finalized and approved
- ✓ Recruit and enroll ten manual wheelchair users (MWU)
- ✓ Pilot study completed

Q4 Goal – Prepare proposal for MW-VC Clinical trial

- ✓ Protocol finalized
- ✓ Data analysis
- ✓ Grant proposal submitted

Comments/Challenges/Issues/Concerns: Nothing to report.

Budget Expenditure to Date

Projected Expenditure: \$148,922.00

Actual Expenditure: \$147,117.85

Identification of Pressure Relief Maneuvers Using Changes in Center of Pressure

S. Andrea Sundaram^{1,2}, Garrett Grindle^{1,2}, Ben Gebrosky¹, Josh Brown¹, Rosemarie Cooper^{1,2}, Rory Cooper^{1,2}

¹Human Engineering Research Laboratories, Department of Veterans Affairs, Pittsburgh, Pennsylvania;

²Department of Rehabilitation Science and Technology, University of Pittsburgh, Pittsburgh, Pennsylvania;

ABSTRACT

Manual wheelchair users are at high risk of developing pressure ulcers. To try to prevent the development of PU, clinicians recommend regular weight shifts, but MWU don't always follow this advice. In order to develop a useful smartphone application to coach MWU to do effective pressure reliefs, it is necessary to accurately identify seating postures.

This paper briefly describes a sensor system for tracking MWU seated center of pressure, and presents representative data obtained from the sensor system while study subjects did forward, leftward, and rightward leans, as well as lifting off the chair. With appropriate filtering, this data can be combined with clinical expertise to produce an artificial intelligence algorithm that identifies types of PR maneuvers, and provides a logical way to quantify their degree. Incorporating the algorithm into a coaching app can continue the education for MWU on how to do effective PR beyond the acute rehab phase, and lead to positive pressure relief behaviors that will reduce the incidence of sitting related pressure ulcers.

Characterizing Quantum Tunneling Composite for Use in the Manual Wheelchair Virtual Seating Coach

Katherine Thanyamongkhonsawat^{1,3}, Andrea Sundaram^{1,2}

¹Human Engineering Research Laboratories, Department of Veterans Affairs, Pittsburgh, Pennsylvania;

²Department of Rehabilitation Science and Technology, University of Pittsburgh, Pittsburgh, Pennsylvania;

³Department of Biomedical Engineering, University of Texas at Dallas (UTD), Richardson, Texas

INTRODUCTION

There are about 3.6 million wheelchair users in the United States [1]. Wheelchair users are at risk of incurring pressure ulcers, which result from constant pressure on the skin by staying in one position for an extended amount of time [2]. The prevalence of pressure sores in the United States is about 13% and treatment can cost up to \$70,000. Clinicians recommend periodic weight shifting (every 15-30 minutes) for pressure management and decreasing the chance of developing pressure ulcers, but it was found that only about 20.8% of manual wheelchair users (MWU) do so once an hour with the rest of the subpopulation having an even lower frequency [3]. Currently, there are various tools that provide regular reminders to perform pressure relief but fail to improve compliance or evaluate the effectiveness of the action [4].

The Manual Wheelchair Virtual Seating Coach (MW-VSC) is an extension of previous work on a Power Seat Function Virtual Seating Coach that implements intelligent reminders and evaluation of pressure relief actions [5]. It is a smartphone app that tracks the user's center of pressure and reminds users to complete a pressure relief. It maps pressure with a system of strain gages under the seat pan. While this system performed well at measuring the user's weight shifts, the materials and set up time for the implementation are cost prohibitive. A cheaper alternative to strain gages, such as quantum tunneling composites (QTCs) for 10 cents per pill, is desired.

QTCs are composite materials consisting of an insulating elastomeric binder and irregularly-shaped metal particles (100nm-500nm) dispersed throughout the binder without contact with other metal particles [6]. QTC resistance decreases with deformation, so they can act as pressure or force sensors. They utilize quantum tunneling. Uncompressed, they act as a perfect insulator with infinite resistance. When compressed, the metal particles are pushed closer together (with no contact), which increases the probability of an electron from one metal particle tunneling through the polymeric material to another metal particle, establishing conductance. QTCs demonstrate a relationship of logarithmic decay between resistance and amount of force applied; their resistance decreases sharply towards 0Ω to become a near-perfect conductor as deformation increases.

However, QTC are not well documented otherwise. Peratech suggests that the load that elicits maximum response from the QTC is 100N or about 22 pounds [7]. Hence, the objective of this study is to characterize QTC to evaluate their viability as pressure sensors for the MW-VSC.

METHOD

Setup

The parameters of data collection include voltage vs. weight and hysteresis. These were observed for individual QTCs and for two QTCs stacked one atop another. A QTC pill is 3.6mm x 3.6mm x 1mm. Tests were conducted at room temperature.

Two flat blocks (one plexiglass, one wood) each had 3 copper strips (50mm x 5mm x 75 μ m) taped to the block with space exposed for placing the QTCs on the inner ends to configure an equilateral triangle of length 1 inch, as seen in Figure 1. These positions will be referred to as Single QTC # or Stacked QTC #, where # = 1, 2, or 3 in correspondence with the labels in Figure 1A. The load was placed in the center so that the weight was

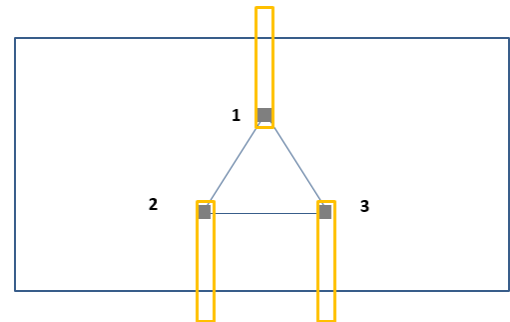


Figure 1. Configuration of the QTCs on each block with positions numbered and copper tape on each block.

evenly distributed among the three QTCs. The QTCs were sandwiched between the two blocks and integrated into a voltage divider.

A program was written in C, the flow of which is illustrated by Figure 2. Voltage was measured by the Pmod AD2, a 4-channel, 12-bit analog to digital converter (ADC). The ADC transmitted data to the Raspberry Pi 3 over the I²C bus. The timestamp of each measurement and the voltage over each QTC were written to a text file for data analysis. The system continuously collected data at a rate of 240Hz until Button 2 was pressed. Button 1 was used to record the time at which a weight was added. A DC voltage source of 5.48V from the raspberry Pi provided power to the QTC system prototype. If the QTC is uncompressed, then the voltage read in the ADC would be 0V or close to 0V. If the QTC is as deformed as possible, the ADC would read about 5.5V.

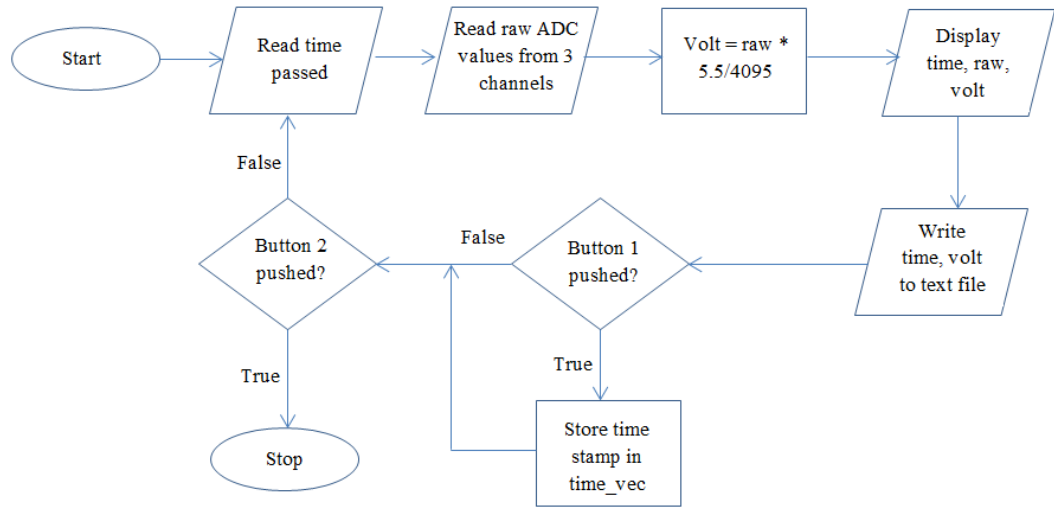


Figure 2. Block Diagram of Program

Data Collection

Five trials were conducted. Based on available weights, voltage was observed for the following forces in pounds 0, 2.2, 11, 21, 29.8, and 54.8. Weight was added about every 30 seconds; a button was pushed when a weight was added to obtain the timestamp of the addition. Then weight was removed (from 54.8 to 29.8 and so on) every 30 seconds for determination of hysteresis. One trial overall is 5.5 minutes. Data collection is stopped with the push of Button 2.

RESULTS

Plotting QTC voltage (in terms of volts) over time (in terms of milliseconds) on Excel yielded scatter plots that remain relatively steady for no weight and for max weight applied, but demonstrated a notable amount of scatter in between, as seen in Figure 3 for QTC Position 2. Each position for both single and stacked demonstrated a similar trend. For further analysis, the QTC voltage for each weight was averaged over the weight's respective time interval, yielding 6 points for each half trial. They were plotted against weight in terms of position and a best-fit exponential curve was applied to the plot in MATLAB, as seen in Figure 4. Error bars represent the standard deviation of each point. The standard deviation tended to be

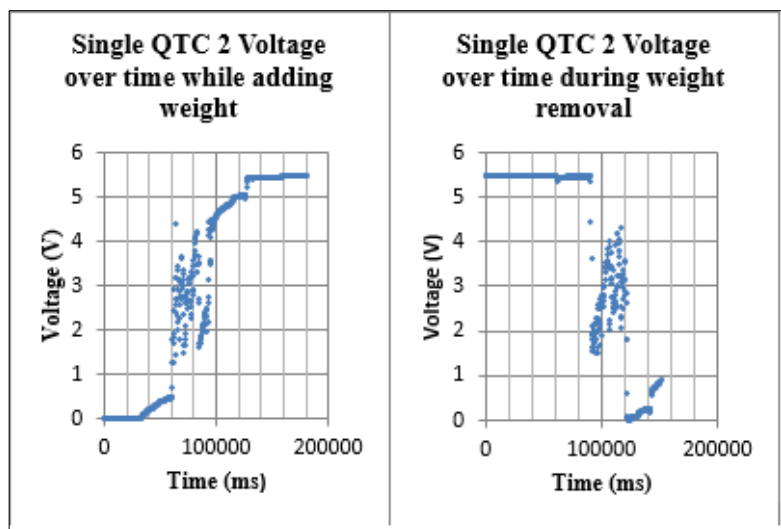


Figure 3. Raw data of voltage over time for QTC Position 2

larger during the adding weight phase, particularly during the first half. Standard deviations tended to be very close to zero- on a scale of hundredths- when there was maximum load applied to the QTCs.

The R^2 coefficient determined by MATLAB conveyed how well the curve fits the data. The equation of the best-fit curve and the R^2 coefficient for each QTC position are listed in the legend of each graph in Figure 6. Each curve demonstrated high correlation, with R^2 being 1 or close to 1, between voltage and weight in the form of ($V = a e^{-bx} + c$), or V equals a times e to the product of negative b and x, and that is summed with c. The quantity x is the weight of the load in terms of pounds.

The lowest R^2 coefficient was 0.9622 with QTC Stack 2 for weight removal. A one-way ANOVA ($\alpha = 0.05$) test on the averages over each QTC position, individual or stacked, revealed that there are no statically significant differences among them.

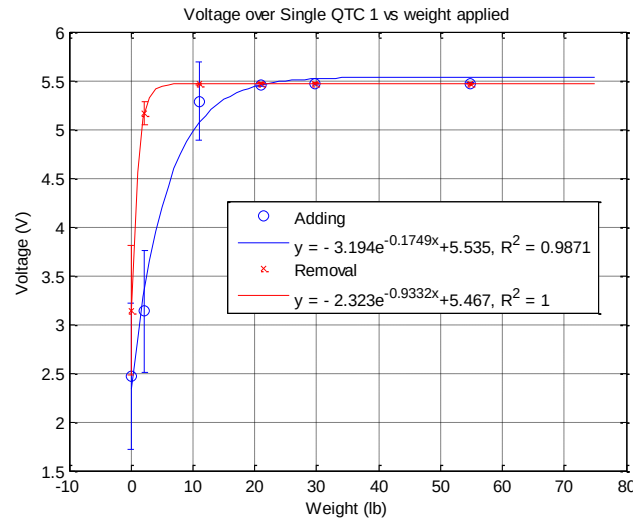


Figure 4. Voltage vs weight of QTC Position 1 (Individual)

The data also demonstrated some hysteresis, shown in Table 1. Hysteresis for a QTC position was obtained by finding the difference between the area under the curve for when weight was added and for that of when weight was removed. When weight is being removed, there is a delay in the QTC uncompressing compared to compression from when weight was being added.

Table 1. Hysteresis of QTC (individual or stacked) at each position

QTC Position	Hysteresis	
	Individual	Stacked
1	13.7096	9.8591
2	52.2823	17.9518
3	33.9639	23.1384

DISCUSSION

As seen in Figure 3, the raw data shows the QTCs' response saturating under load, and hence they would be more ideal to be used as switches rather than sensors for pressure mapping. The flattened response after 21 pounds, or after about 90 seconds, is not ideal as wheelchair users exert over 50% of their body weight on the seat pan [8].

The extent of the hysteresis demonstrated may also affect the QTCs' viability for the MW-VSC. Pressure would be continuously exerted in the seat pan, which would continuously compress the QTC pills unless there were additional structural components added such as springs or stands. With the pills in a continuously compressed state, the pressure tracking would be skewed for the next scheduled pressure relief action.

The data could have been affected by a variety of factors. The weight may not have been exactly centered, though this may more accurately reflect reality as everyone sits naturally with their unique pressure distribution. The copper tape used may also have minute deformations in the form of wrinkles that could affect the QTC's voltage at a particular weight, so care is necessary to minimize wrinkles during placement of the strip. Based on the fluctuations, the lighter weights may not also have been steadily placed on the testbed, which detracts from wholly characterizing the QTC. In terms of the MW-VSC however, this is not as big of a problem since half of the average human weight is about 50 to 70 pounds. However, as aforementioned, the QTC response peaks after 21 pounds. Wood is also pliable compared to plexiglass, so using a wooden block as a base may have contributed to additional deformation of the QTC, so both blocks should be plexiglass. An advantage to using plexiglass, other than its stiffness, is that its transparency allowed a bird's-eye view of the placement of the QTC and whether they shifted off the copper strip.

CONCLUSION

Quantum tunneling composites (QTCs) are polymer-metal composites with potential for various applications, particularly as pliable, small, inexpensive switches. While there were numerous limitations, the QTCs behaved as expected, as supported by the multiple curve fits with high correlation. The results support that QTC pills would not be viable as sensors for the MW-VSC. This system may work for children, who weigh less than adults. The resemblance to a switch is not desired, so other sensors should be considered. Other alternative sensors that may be used include: SEN-10-245 load sensors sold by SparkFun or the LPS25HB sold by STMicroelectronics, which can handle 40-50kg and 26-126kPa respectively [9,10].

Further characterization of the QTC pills include: settling time, time to return to uncompressed state, deformation characteristics and relationship between resistance and linear displacement.

ACKNOWLEDGEMENTS

The contents of this paper do not represent the views of the Department of Veterans Affairs or the United States Government. This research was supported by the Human Engineering Research Laboratories at the University of Pittsburgh. It was made possible through the support of the National Science Foundation (NSF)'s grants EEC 0545865, 1063017, and 1262670, and also CDMRP grant W81XWH-17-1-0620.

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