

**DEVELOPMENT OF A WHEELCHAIR CUSHION COVER WITH MICROCLIMATE
MANAGEMENT TO PREVENT PRESSURE INJURIES**

by

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Pressure injuries are a common medical problem that negatively influences mortality, causes financial burdens, and reduces quality of life for people with spinal cord injuries or other mobility impairments. Wheelchair seat cushion designs are developed to reduce risk factors for pressure injuries. Pressure, shear and friction are the primary causative factors known to increase pressure injury risk. Other factors include heat and moisture. Current preventive approaches related to seat cushions focus on reducing pressure, shear, and friction. The important heat and moisture factors are seemingly overlooked.

Options to manage microclimate at the support surface interface are limited. This study aims to develop a wheelchair cushion cover, which provides currently available wheelchair cushions with an advanced feature to improve microclimate management by reducing heat and moisture at the body-seat interface to help prevent pressure injuries.

The development of the wheelchair cushion cover with microclimate management included the following steps: generating a design specification, developing three design concepts, fabricating a prototype, evaluating the cover and conducting focus group interviews. The prototype cover was modeled on mattress low air loss features and its function was applied to wheelchair cushions. The cover was intended for use with the existing cushion and cover.

Evaluation of the prototype cover was performed and focused on quantifying the microclimate control features. A thermodynamic rigid cushion loading indenter simulated the

environmental conditions of a human body on three cushion types for 3-hour tests. Comparing results for the three cushions with and without the prototype cover demonstrated significantly lower relative humidity after 1 hour ($p < 0.002$). No significant difference in temperature ($p > 0.002$) was found for the entire test session. Standardized cushion characterization tests showed that the prototype cover provided additional pressure distribution ($p < 0.002$) compared to the three test cushions without the new cover. This study included focus group interviews to gather feedback regarding the prototype cover. The cover received an overall positive response from participants. All participants agreed with the utility of a microclimate management feature and necessity of the product. They would recommend the cover to wheelchair users.

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PREFACE

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1.0 INTRODUCTION

Pressure injuries are one of the most common medical challenges that negatively influence patient mortality, financial burdens for patients, their families and the health care system, and quality of life (Bauer et al., 2016; Leaf Healthcare, 2014; Padula & Delarmente, 2018). The prevalence of pressure injuries in acute care in the United States represents 0% to 15.8% (Goldberg, 2012) and prevalence rates of long-term care range from 8.2% to 32.2% (Pieper, 2012). Annually approximately 2.5 million patients require treatment for pressure injuries (Reddy et al., 2008) and the annual costs of treating pressure injuries are estimated at \$3.3 to \$11 billion (Brem, Maggi, & Nierman, 2010; Van Den Bos, Rustagi, & Gray, 2011). Based on a simulation model about the daily accumulation of costs to treat hospital-acquired pressure injuries (HAPI), an analysis shows that the cost of the HAPI could estimate \$10,708 per patient and exceed \$ 26.8 billion in the United States (Padula & Delarmente, 2019). Pressure injuries lead to increased health care utilization for their medical management of pressure injuries due to loss of function, infection, and a lengthy hospital stay (Pieper, 2015). More than half of patients with pressure injuries received long-term care, which has more than three times hospitalization rates for all other causes (Russo, Steiner, & Spector, 2008). For these reasons, it is essential to research and develop practical guidelines for the pressure injury prevention using advances in medical technologies, which need to be enhanced to realize improvements in quality of life, reduce the recovery time and relieve economic burdens.

Wheelchair seat cushion designs are developed to reduce risk factors for pressure injuries. Pressure is a major causative factor, along with other factors such as shear, friction, heat ,and moisture, known to increase pressure injury formation (Pieper, 2015). With advanced

technologies, cushion manufacturers continue efforts to incorporate new strategies pressure redistribution, shear and friction reduction, and dissipation of heat and moisture. Most of the technologies focus on reducing pressure, shear, and friction. The reduction of heat and moisture seems to have been overlooked.

The wheelchair cushion cover developed here has been designed with an advanced feature to improve microclimate management characteristics and configured so that it is usable with a broad range of commercially available cushions. This novel microclimate management feature, called low air loss (*National Pressure Ulcer Advisory Panel Support Surface Standards Initiative Terms and Definitions Related to Support Surfaces*, 2018), provides currently available wheelchair cushions with the additional function to reduce moisture between the user and cushion surface thus reducing the risk of developing pressure injuries.

2.0 BACKGROUND

2.1 PRESSURE INJURIES

2.1.1 Definition of Pressure Injuries

The National Pressure Ulcer Advisory Panel defines a pressure injury as a localized injury to the skin and/or underlying tissue, usually over a bony prominence, due to localized pressure or pressure in combination with shear. While pressure injuries are linked to a number of contributing or confounding factors, the importance of these factors has not been yet elucidated (NPUAP, 2014). Pressure injuries commonly develop over a bony prominences such as the sacrum, ischial tuberosity, trochanter, or calcaneus, although they may occur anywhere on the body (Pieper, 2015). The most common anatomical locations for pressure injuries to present is in the vicinity of the sacrum or coccyx, on buttocks, and on the heels (Van Gilder, Amlung, & Harrison, 2009). Weight bearing bony locations such as these are more susceptible to pressure injury because these sites concentrate the forces of a person's body weight between the unyielding surface of a bone and whatever external surface is supporting the weight. This mechanical loading leads to deformation of the tissue which can cause ischemia and excessive cellular distortions. The risk of injury due to these effects is greater for older people with atrophy of muscle and other subcutaneous tissue. A reduction in thickness and resiliency of tissue surrounding the coccyx, sacrum, and heel is particularly critical as it exposes those regions to potentially damaging forces and explains why these regions are common sites for pressure injuries (Pieper, 2015).

2.1.2 Etiology of Pressure Injuries

Pressure is widely known as an important factor in pressure injury formation. Several other factors are also relevant for determining whether pressure is sufficient to cause tissue death by creating tissue ischemia and cell death (Gawlitta et al., 2007; Dealey et al., 2015; Pieper, 2015). The pathologic effect that originate from excessive pressure on soft tissue can be explained by pressure intensity, pressure duration, and tissue tolerance (Pieper, 2015).

2.1.2.1 Pressure Intensity

Pressure intensity related to pressure injury risk has been traditionally associated with capillary closing pressure. Kumar, Fausto, and Abbas (2005) measured normal hydrostatic pressure of approximately 32 mm Hg in the arterial capillaries and 12 mm Hg in the venous capillaries. The colloidal osmotic pressure at the mid capillaries was found to be approximately 25 mm Hg. Hence, collapsing a capillary requires just minimal (12 to 32 mm Hg) internal pressure (Burton & Yamada, 1951). The external pressure required to collapse a capillary vessel would likely be higher dependent on the mechanical properties of the surrounding tissue and other mechanical and physiological factors. Numerous studies have measured interface pressures (Kosiak, 1961; Kosiak, Kubicek, & Olson, 1958; Lindan, 1961) and have shown that interface pressures were commonly much higher than capillary pressures for people in sitting or supine positions (Bennett et al., 1984). Interface pressures high enough to close capillary vessels and cause ischemia does not always lead to tissue damage because people with normal sensations and motor function can shift their body weight in response to the resulting discomfort and effectively reperfuse the tissue before irreversible damage results (Pieper, 2015). However, people with spinal cord injuries or with other mobility and sensory impairments may not recognize the discomfort.

For wheelchair users, risk due to intensity of pressure during sitting is most common in the tissue surrounding the ischial tuberosities and sacrum/coccyx where concentration of stress and strain causes ischemia and excessive deformation. (Olesen, de Zee, & Rasmussen, 2010).

Pressure intensity is also related to damage of soft tissue attributable to deformation independent of ischemia. Recent work by Gawlitta et al. (2007) investigated compression at the cellular level. More specifically, the study observed tissue of bio-artificial muscle for three levels of compression 0, 20, and 40 % strain, under normal and hypoxic conditions. The results indicated that cell death was not caused by hypoxia over a 22-hour period. However, cell death could result from compression in much less time compared to damage resulting from ischemia. The study demonstrated that injury of distorted tissue could occur independent of ischemic damage (Gawlitta et al., 2007).

2.1.2.2 Pressure Duration

Pressure duration is a major factor that influences the detrimental effects of pressure and is associated with pressure intensity. An inverse relationship is present between pressure duration and intensity related to development of tissue injury due to ischemia. Although high-intensity pressure can cause tissue damage over a short period of time due to disrupted cellular function, low-intensity pressure can cause tissue damage over a long period due to ischemia (Kosiak, 1961; Oomens et al., 2015). The timeframe for the ischemic pathway to damage was demonstrated by Hussain, et. al. in an experiment where they observed that a pressure of 100 mm Hg applied for 6-hours resulted in more damage than a 2-hour test with the same loading conditions. (Hussain, 1953). Different ischemic injury thresholds on duration is noted for muscle, fat, and skin, as each tissue resists periods of ischemia differently. For example, muscle tissues are more vulnerable to tissue degeneration than skin tissue (NPUAP, 2014). Investigation of the relationship between

pressure duration and risk associated with direct cellular deformation and resulting cell has focused on determining a time and strain threshold for muscle tissue (Gefen et al., 2008). The series of studies has established a relationship between strain, time and cell death, as well as confirming Kosiak's research regarding pressure and time for ischemic injury.

2.1.2.3 Tissue Tolerance

Tissue tolerance indicates how much pressure the skin can resist. In animal studies, sensitized rat muscle was loaded with a pressure of 100 mm Hg applied for 2 hours. Seventy-two hours later, muscle degeneration occurred in only 1 hour when 50 mm Hg pressure was then applied to the same tissue (Husain, 1953). This finding suggests that for muscle applied to multiple pressures, any load of intensity negatively affects tissue tolerance regardless of specific spans of time (Pieper, 2015). Therefore, small loads could lead to dermal structure changes that appear minor on the surface, even if the damage occurs in deeper tissue layers (Edsberg, 2007). The ability to withstand pressure of the skin and underlying structures, such as collagen, interstitial fluid, and blood vessels, has an impact on tissue tolerance by working together to transmit the load to the tissue surface similar to a set of parallel springs (Krouskop, 1983). The tolerance of the soft tissue to pressure is linked to several intrinsic and extrinsic factors (Pieper, 2015). The extrinsic factors that affect tissue tolerance include shear, friction, and moisture. The tissue tolerance is also related to intrinsic factors, such as nutrition, age, blood pressure, stress, smoking and temperature, among others (Pieper, 2015).

2.2 MICROCLIMATE RELATED TO PRESSURE INJURIES

2.2.1 Definition of Microclimate

Microclimate can be defined as the climate in a local region which differs from the climate in the surrounding region. It is comprised of factors such as temperature, humidity, and airflow (Imhof et al., 2009). The term used in many scientific fields, such as botany, architecture, zoology, and aeronautics (Kottner et al., 2018). For the wheelchair cushion, microclimate is represented by local tissue temperature and relative humidity at body-support surface interface (NPUAP, 2014).

2.2.2 Microclimate Effects on Skin

As a layered tissue, the skin is composed of epidermis and dermis. The stratum corneum (SC) is defined as the outermost layer of the epidermis, and functions as a biological barrier (Elias, 1981). The SC covers most body surfaces comprising 15 tightly stacked layers of corneocytes (Zhen, Suetake, & Tagami, 1999). The normal SC barely enables the passage of small molecules such as moisture. While the transepidermal water loss (TEWL) in normal skin is only 2-5 grams per hour per cm², TEWL values in abnormal SC are much higher (Nilsson, 1977). The SC plays a significant role in the skin surface in order to maintain flexible and smooth skin by binding water, even if the skin is exposed to a dry environment (Tagami et al., 2001). Therefore, as the first dermal layer, the SC is directly influenced by microclimate changes which affect the skin's barrier function related to its mechanical properties (Fluhr et al., 2008; Pedersen & Jemec, 2006; Tagami et al., 2001).

2.2.3 Humidity Effects on Tissue Tolerance

The level of relative humidity (RH) for the environment to which the SC is exposed increases or decreases SC hydration as the SC is able to absorb and desorb water (Coleman et al., 2013; Egawa et al., 2002; Gerhardt et al., 2008). The equilibrium hydration of the SC ranges from relative humidity (RH) of 40% to 60%, although SC hydration dramatically increases above RH 60% (Imhof et al., 2009). Increased SC hydration results in swelling, increased thickness of the SC, and changes to the skin surface (Dobos et al., 2015; Igaki et al., 2014; Warner, Stone, & Boissy, 2003). This property of the SC hydration is related to RH and plays an important role in tissue tolerance.

Increased SC hydration increases the risk for irritation and contact dermatitis, which are especially linked to incontinence (Blattner et al., 2014; J. Kottner & Beeckman, 2015). A high level of RH results in a decrease of SC stiffness, elasticity, and mechanical strength. In long-term exposure with overhydration of the skin surface, the SC's status is compromised and the SC may become macerated (Wilkes, Brown, & Wildnauer, 1973).

Decreased SC hydration contributes to skin dryness (Wilkes et al., 1973). Dry skin is prone to mechanical damage, fissures, cracks, and inflammation, which increase the risk of tissue injury since increased stiffness diminishes the effective contact area and increases localized stress (Atlas et al., 2009; Engebretsen et al., 2016).

Elevated moisture on the skin can affect its frictional resistance (Gerhardt et al., 2008). The skin becomes macerated in elevated skin moisture levels, which can cause loss of mechanical strength, increase risk of infection, or result in greater susceptibility to skin injury (Faergemann et al., 1983; Mayrovitz & Sims, 2001; Nakgami et al., 2006). Excessive moisture in combination with pressure can produce additional damaging effects. Skin under high moisture conditions has a

higher coefficient of friction than skin under dry conditions. Skin in high humidity reveals an increase in friction and causes a person to stick to the seat interface (Knapik et al., 1995; NPUAP/EPUAP/PPPIA, 2014). A direct positive association has been demonstrated between RH, SC hydration, and the coefficient of friction (Bhushan, Chen, & Ge, 2012; Gefen, 2011; Gerhardt et al., 2008). Skin friction is high in wet and dry conditions (Adamset al., 2007; Kovalev et al., 2014). However, a high moisture environment increases the coefficient of friction between the skin and the contact area (Persson, Kovalev, & Gorb, 2013). The more the contact area sticks to the skin, the greater the deformation and shear (Sopher & Gefen, 2011). Schwartz et al (2018) have developed a computer model to map the effect of humidity on skin friction against medical textiles as it relates to the formation of pressure ulcers. The wetness between the skin and medical textile increases risk of developing pressure injuries.

2.2.4 Temperature Effects on Tissue Tolerance

A high temperature at the skin surface leads to a temperature increase of the SC, which is associated with increased SC hydration (Cravello & Ferri, 2008; Igaki et al., 2014). The skin temperature increase is also connected to increased perfusion, which may be linked to a protective mechanism to avoid local overheating (Petrofsky et al., 2012). The result of increased skin temperature is accelerated heat transport to deeper tissue layers. Controlled animal studies have explained that increasing skin temperatures result in a higher susceptibility to the development and severity of pressure injuries (Kokate et al., 1995). Such studies were conducted with indenters at temperatures of 25, 35, 40, and 45°C, which were simultaneously applied to the skin surface with a contact pressure at 100mmHg over 5-hour periods. They were then monitored in 4 weeks. All temperatures above 25°C reveals moderate to severe tissue damage (Kokate et al., 1995).

Lachenbruch (2005) presented a generalized model estimating combined effect of pressure and temperature based on prior studies including Kokate's study. A reduction of 5°C in the skin-support surface interface would contribute to tissue protective effects similar to reducing the magnitude of the interface pressure by pressure distribution surfaces. However, the hypothesis remains unknown. Patel et al. (1999) studied the local tissue response of increased or decreased temperature with pressure, perfusion, and stiffness. Their study indicated that higher temperature causes increased tissue stiffness, decreased ability to manage proper blood flow, and poor loading distribution, which leads to the formation of pressure injuries. Moreover, to increase body temperature, it is required to increase oxygen and energy in the tissue. A body temperature increase of 1°C can raise metabolic activity by 10 %. The metabolic demand might negatively influence ischemic tissue (Fisher et al., 1978). Therefore, the reduction of skin temperature could reduce the formation of the pressure injuries.

3.0 PROBLEM STATEMENT

The purpose of a wheelchair cushion is to provide comfort and protection for wheelchair users by reducing pressure at support surfaces, a function which has been effective in decreasing the risk of pressure injury (Brienza & Geyer, 2000; Brienza et al., 2010). A support surface is defined as any “specialized device for pressure redistribution designed for management of tissue loads, micro-climate, and/or other therapeutic functions (i.e. any mattresses, integrated bed systems, mattress replacements, overlay, seat cushion, or seat cushion overlay)” (*National Pressure Ulcer Advisory Panel Support Surface Standards Initiative Terms and Definitions Related to Support Surfaces*, 2018).

However, most wheelchair cushion manufacturers focus on reducing pressure, shear, and friction in order to prevent pressure injury development. The current options for managing microclimate at the cushion interface are limited as few companies have released wheelchair cushions with microclimate management. For example, AireRx (Andex Healthcare, Sweden) is a wheelchair cushion with a fan, which provides multi-density construction with pelvic stability. The AireRx fan is located in the front of the cushion. When the fan operates, air is supplied to the seat interface, and the spacer material is used as an air passageway for cool air to replace hot, moisture-filled air as demonstrated in Figure 1. Another example is the APK2 (Aquila Corporation, Holmen WI) which provides an automatic alternating pressure wheelchair cushion. The function of the moisture control unit in APK2 allows the wheelchair user to remain cool and dry due to the imbedded fan inside the front of the cushion (Figure 1). Yet, the problem of these products is they are intended for use with specific types of cushions. Nevertheless, many wheelchair cushions on the market, would benefit from microclimate management in order to prevent pressure injuries.

Thus, by combining a pressure distributing wheelchair cushion with controlled microclimate management, such a medical intervention could improve protection of the skin for wheelchair users at high risk for pressure injury.



Figure 1. AireRx (Left) and APK2 – Moisture Control Unit (Right)

4.0 SPECIFIC AIMS

The purpose of this study was to develop a prototype wheelchair cushion cover with microclimate management for pressure injury prevention. First, the aim of the wheelchair cushion cover was to improve microclimate at the seat interface for wheelchair users, by reducing heat and moisture. Second, the wheelchair cushion cover was compatible with currently available wheelchair cushions and did not negatively affect other wheelchair cushion performance characteristics.

Specific Aim 1 – Develop and fabricate prototype wheelchair cushion cover

Specific Aim 2 – Evaluate and validate microclimate control features of prototype with respect to

- Heat and moisture dissipating characteristics
- Pressure distribution characteristics

5.0 PRODUCT SPECIFICATION

The design process must establish a set of precise, measurable specifications for the product and its function. The product specification must satisfy the customer. The user needs-technical requirements matrix (Table 1) details the relationship between user needs and technical requirements. This matrix, known as *House of Quality*, is a graphical technique used in *Quality Function Deployment* that easily communicates design specification by listing user needs as they relate to the list of technical requirements (Ulrich & Eppinger, 2000). By associating user needs and technical requirements, design criteria are clarified and can improve the wheelchair cushion cover for microclimate management.

Table 1. The User Needs-Technical Requirement Matrix

User Needs		Technical Requirements										
		1	2	3	4	5	6	7	8	9	10	11
		Reduction of skin temperature	Reduction of skin relative humidity	Time to reach target humidity	Pressure redistribution	Weight of cover	Cover material	Installation and operation time	Average battery life	Noise level	Durability	Voltage requirement
1	Microclimate management by circulating air over the seating area	●	●	●			●					
2	Low-profile interface that does not affect pressure distribution				●	●	●					
3	Compatible with current cushions				●	●	●					
4	Long battery life								●			●
5	Portable					●						
5	Durable										●	
6	Washable and cleanable						●				●	
7	Easy to use							●				
8	Comfortable				●			●				
9	Low noise									●		
10	Lightweight					●						
Technical Requirement Unit		°C	% RH	min	mmHg	gram	-	min	hour	dB	month	V
Technical Requirement Target		30	40~60	15	*	500		5	8	30	18	12

* No significant changes in seat cushion performance measures per ISO 16840 test methods

The user needs-technical requirements matrix is composed of user needs and technical requirement and were developed based upon the literature and observations in the clinic. Given the rating results in the cells between user needs and technical requirement, the bullet mark in the cell demonstrates that the user needs and technical requirement are associated. The results of the matrix illustrated the important features to concentrate on managing skin microclimate, maintaining skin protection properties, and maximizing compatibility with current cushions. The design criteria have been summarized in Table 2. Following the design criteria, the design process was conducted including design concepts, prototype fabrication, and testing.

Table 2. Design Criteria

No.	Technical Specification	Unit	Value
1	Reduction of skin temperature	°C	30
2	Reduction of skin relative humidity	% RH	40~60
3	Time to reach target humidity	min	15
4	Pressure redistribution	mmHg	*
5	Weight of cover	gram	500
6	Cover material	-	-
7	Installation and operation time	min	5
8	Average battery life	hour	8
9	Noise level	dB	30
10	Durability	month	18
11	Voltage requirement	V	12

6.0 CONCEPT GENERATION

After the problem of the wheelchair seat cushion was identified, possible solutions were generated. Three ideas were selected, and their respective sketches were drawn. This section first provides detailed descriptions of these three ideas for the wheelchair seat cushion cover and then discusses the advantages and disadvantages of each.

6.1 INITIAL CONCEPT

6.1.1 Concept Description

The first concept was divided into two parts, similar to the assembly of the powered air ventilation and the cushion cover, as presented in Figure 2. The assembly of the powered air ventilation consisted of the fan for an air source and the air outlet to distribute air in the seat. Air outlet holes were located on the cushion contact surface of the wheelchair user in order to help air circulate efficiently. The material was a plastic sheet inside an air cap for the airway from the fan. The switch was located in bottom of the fan and could be operated with a battery. Another aspect of the concept was the cushion, which combined the assembly of the power air ventilation. The assembly could change from in or out of the underside of the cushion surface. This allowed the cover to be washable and cleanable by separating the assembly part. The cover material would be a mesh fabric which enables air to pass through the cover.

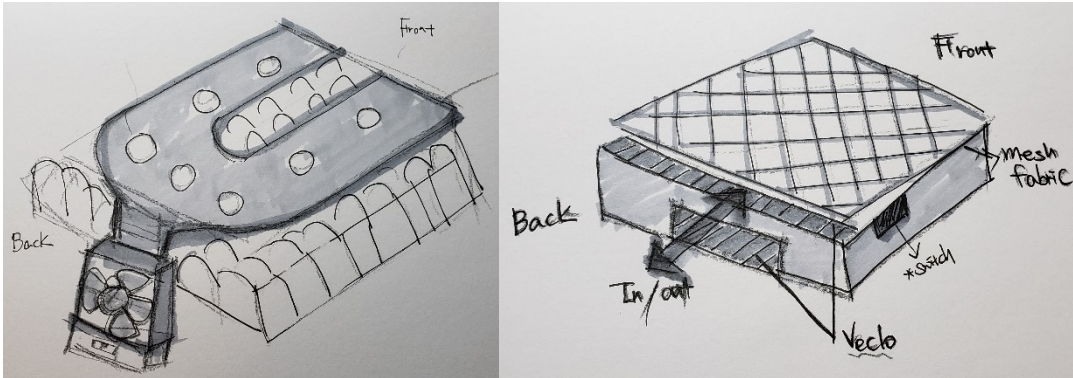


Figure 2. Initial Concept Sketch

6.1.2 Concept Advantages

The advantage of this concept was that the assembly of powered air ventilation provided air delivery to specific targets for microclimate management. This concept met the criteria of air circulation over the sitting area, since the holes of the airway were located on the sitting surface. Another advantage of this concept was that the assembly of air powered ventilation and the cover were removable. As such, those parts could be cleaned and washed separately.

6.1.3 Concept Disadvantages

This concept had several disadvantages. First, the holes of the airway might be blocked by loading condition with wheelchair users as wheelchair cushions encompass the contour of the buttock due to pressure distribution (Sprigle & Press, 2003). The fan position would be an issue, since the space was insufficient at the backside of the cushion for wheelchair users to sit on their cushion. Lastly, the holes of the airway might negatively influence hygiene due to sweat, urinary or fecal incontinence, and drainage from wounds.

6.2 THE SECOND CONCEPT

6.2.1 Concept Description

The following design improved upon the first concept design by solving specific problems. A number of manufacturers have developed novel fabric technologies to facilitate the transport of moisture away from loaded body sites and accelerate active air flow at the patient-support surface interface (Worsley & Bader, 2018). Based on this development, the second concept was designed to utilize vapor permeable material so that any water, urine, and fecal material that contacted the seat of the wheelchair user could be transferred to the airway underneath the cover. The spacer material was placed in the airway so the air could circulate, even when the wheelchair user was seated (Xiaohua, Hong, & Xunwei, 2008). Fans that help air circulation were attached to facilitate air supply and exhaust through the airway under the outer cover. The cover material without the vapor permeable material could use an elastic material, which can be stretched in lateral directions (Figure 3).

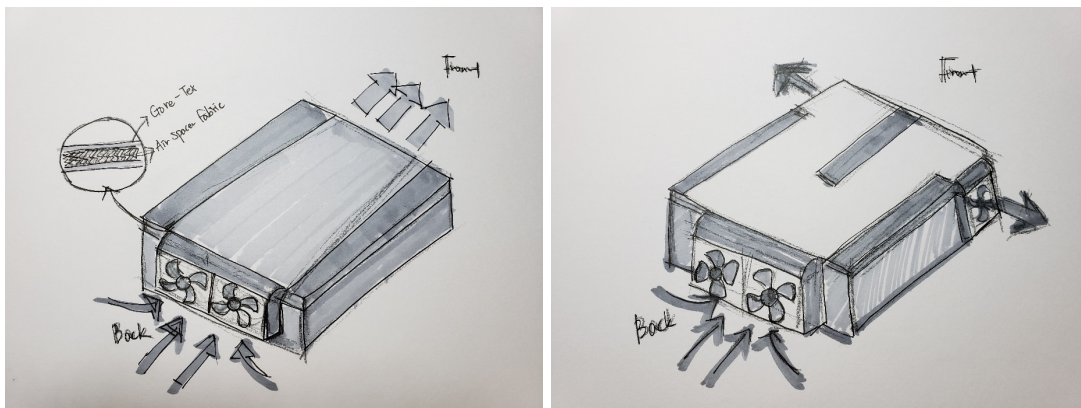


Figure 3. The Second Concept Sketch

6.2.2 Concept Advantages

Unlike the initial design, since the air holes were not exposed, air circulation was not disturbed even if the wheelchair user was sitting on the seat, because the air passages were under the seat interface. The fan position was located on both sides and the back of the cushion, so multiple fans improve air circulation in the air passages.

6.2.3 Concept Disadvantages

The vapor permeable material is not flexible, so it might not be appropriate to use it as the outer material of a wheelchair cushion cover. The additional pressure will be generated in the sensitive area when the tension of the cover increases (Denne, 1981). The cover design could have negatively influenced pressure distribution of the wheelchair cushion. The ventilation function might require too many fans, which does not fit the product specification because it would require too much power. The fans could also generate excessive noise during the microclimate management operation.

6.3 THE FINAL DESIGN

6.3.1 Concept Description

The final design was a wheelchair cushion cover with negative air flow powered by a fan in order to reduce excess moisture from the skin and the surface interface while wheelchair users

sit on their own cushions. The cover was intended to be placed over the original cushion and cushion cover, since the cover is often an integral part of the cushion and affects pressure distribution. The outer layer of the cover was made from a vapor permeable material for drawing away the moisture that builds up from the wheelchair user. The inner layer was made from two-way stretch material in order to reduce shear force. A spacer material served as an airway for extracting outside moisture between the outer and inner layer. The fan was located inside the cover at the front of the cushion, and the back had an air vent for air input and circulation. Negative air flow operated by the fan can extract outside moisture from the airway. The outer layer was designed to completely envelop the top and side of the cushion and allow the cover to conform to the shape of various wheelchair cushions. The bottom part of the cover acted as a pocket for the wheelchair cushion in order to hold the position of the cover and prevent migration between the wheelchair cover and the wheelchair cushion (Figure 4).

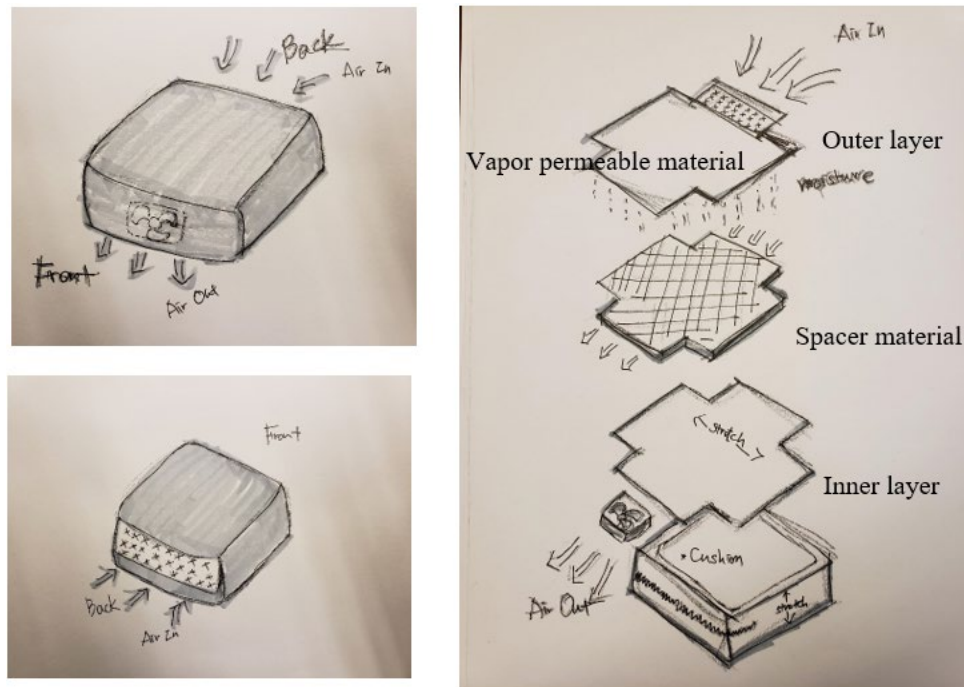


Figure 4. The Final Concept Sketch

6.3.2 Concept Advantages

The design wrapped around the top and sides of the cushion and complemented the disadvantages of the stiff material of the outer cover in order to perform microclimate management without interfering with cushion characteristics such as pressure distribution. In addition, the spacer material also covered the top and side of the cushion to help moisture delivery expand in all directions, even if the airway were obstructed by loading conditions on the seat. The design used a single fan, which extracts moisture from the airway, reduces noise, and requires less power for system operation.

6.3.3 Concept Disadvantages

The design could be bulky through several layers due to enveloping the top and sides of the cushion. As such, the depth and width of the cushion may be increased. Moreover, the cover was not easy to wash or clean since the parts could not be disassembled.

7.0 PROTOTYPE WHEELCHAIR CUSHION COVER

Arjo's Skin IQ hospital mattress provides a simple, effective solution to manage the skin microclimate of patients and thus, help prevent pressure injuries, as depicted in Figure 5 (*Skin IQ Instruction for Use Microclimate Manger*, 2019). This product is intended for use with hospital beds and has already been applied in clinical settings for pressure injury prevention.



Figure 5. Skin IQ

The prototype is a modified the Skin IQ for application to wheelchair cushions. The outer cover of the prototype used the vapor permeable material from the Skin IQ cover. The Skin IQ cover has several benefits, including a greater moisture vapor transfer rate at $130 \text{ (g/m}^2\text{)/hr}$, which has been improved from the average rate of $97.7 \text{ (g/m}^2\text{)/hr}$ of conventional low air loss surfaces (Reger, Adams, Madklebust, & Sahgal, 2001; "Skin IQ | Arjo," 2019). This feature is helpful to transport moisture away from the loaded body site. In addition, the spacer material facilitates air circulation in the system (Worsley & Bader, 2018). A two-way stretch material that provides wheelchair users with shear reduction was used for the inner layer (Jonathan, 2008). The prototype was designed to fit 16x16 inch wheelchair cushion with variable cushion height (Figure 6). The cover must be used with existing cushion and cover for proper use. The prototype incorporated the

fan of Skin IQ, which generated negative airflow to improve laminar airflow. However, the fan had to be plugged into an outlet in order to operate.



Figure 6. Prototype of the Wheelchair Cushion Cover with Microclimate Management Front (Left) and Back (Right) of Cushion Cover

The system mechanism (Figure 7) is similar to low air loss, which describes a feature of a support surface that uses a flow of air to manage the heat and humidity of the skin (*National Pressure Ulcer Advisory Panel Support Surface Standards Initiative Terms and Definitions Related to Support Surfaces*, 2018). Cover material with high moisture vapor permeability allows the cover to transfer the moisture to an air passageway beneath the cover and away from the wheelchair users and seat interface. The fan circulates a continuous flow of air through the air passageway underneath the seat interface. The spacer material provides the air passageway with cool air to replace the hot, moisture-filled air.

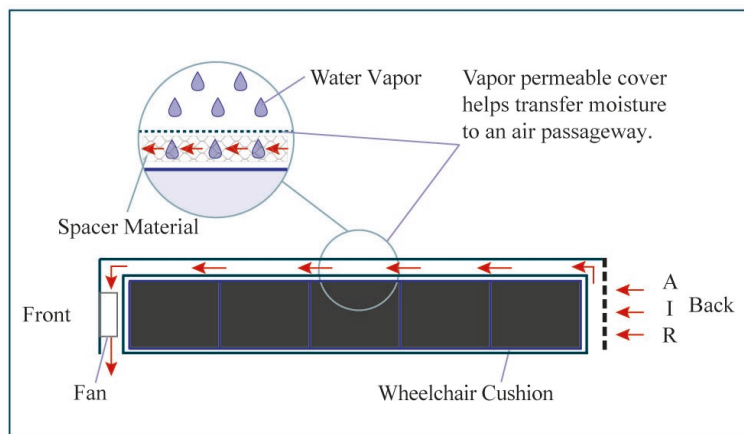


Figure 7. System Mechanism of Prototype Cover

7.1 PROTOTYPE EVALUATION METHODS

To compare the physical and mechanical characteristics of seat cushions with and without the microclimate management cover, the methodologies chosen for this study were loaded contour depth and overload deflection in ISO 16840-2:2018, horizontal stiffness test in ISO 16840-2:2018, Annex C, and interface pressure measurement test in ISO 16840-6:2015. To measure heat and water vapor transmission, a draft test method was used, by ISO 16840-7 Working Draft:2018.

7.1.1 Cushion Selection

The cushions were selected on the basis of healthcare codes established by the Centers for Medicare and Medicaid Services (CMS). The Healthcare Common Procedure Coding System (HCPCS) plays an important role in the healthcare claims of Medicare and other insurance programs for payment. Three cushions were chosen with HCPCS codes E2622 (Skin Protection, Adjustable) or E2624 (Skin Protection and Positioning, Adjustable). Three cushion designs were selected as the wheelchair cushion cover compatibility with microclimate management needed to be checked. All cushions measured 16” by 16” in width and depth. The cushions used in this study are detailed in Table 3.

Table 3. Cushion Selection

Cushion Designation	Cushion	Manufacturer	Cushion Design	HCPCS Code
A	J3	Sunrise Medical	Viscous fluid and Contoured Elastic Foam	E2622
B	Quadtro Select High Profile	ROHO	Segmented Air Cell	E2624
C	Vector	Comfort Company	Independent Air Cell	E2624

7.1.2 Loaded Contour Depth and Overload Deflection

The loaded contour depth (LCD) test measures the immersion capability of a cushion or the ability to accommodate the pelvis (International Organization for Standardization, 2018a). Sprigle and Press (2003) have explained that the LCD test provides a simple way to characterize the wheelchair cushion's performance related to pressure reduction. The overloaded deflection test is designed to reflect the ability of a cushion under overloaded conditions in order to avoid a bottomed-out condition. The overloaded deflection test is conducted by additional weights (33% and 66% over normal test load) from the LCD test to mimic several clinical situations, including the wheelchair users being seated in a certain posture and experiencing weight shift. This also helps determine a longer cushion life (Sprigle & Press, 2003). The test results indicate a margin of the safety, where a higher margin of the safety means the wheelchair user is supported by the cushion even though the cushion has an overloaded condition (International Organization for Standardization, 2018a). The test identified bottoming out condition, which meant the cushion under overloaded condition totally compressed and could not accommodate any further deflection. The test also determined pass and fail for contact of the trochanter buttons under the normal loaded condition using paper to inform if there was contact between cushion and indenter. The test method consists of a loaded contour indenter (LCI), an indenter foot, and a measurement jig, as shown in Figure 8. The indenter foot assembled with the measurement jig is used to measure the cushion thickness. The loaded contour depth jig, which mimics human ischial tuberosities and greater trochanters, simulates the loading conditions by putting weight on the measurement jig (Sprigle & Press, 2003). The immersion of the LCI into the cushion is measured.



Figure 8. The Apparatus of Loaded Contour Depth and Overload Deflection

7.1.3 Interface pressure measurement

Interface pressure measurement helps determine wheelchair cushion performance by measuring the magnitude and distribution of forces under simulated loading conditions (International Organization for Standardization, 2015). Although this method does not make a definitive decision about overall cushion effectiveness, it can be used to compare pressures between wheelchair cushions for individual users (Sprigle, Dunlop, & Press, 2003). The interface pressure measurements were recorded by a force sensing array (FSA) pressure mapping system (Vista Medical: UT1010-7683, Winnipeg, Manitoba, Canada). This method includes an FSA pressure mat, an FSA interface module, a rigid cushion loading indenter (RCLI) as defined in ISO 16840-2, and a data logging device with FSA software, as outlined in Figure 9. The FSA pressure mat is a thin flexible material with an array of 16” by 16”, 1’ by 1” sensors that measure and display visual output of the pressure data by using numerical values with a colored overlay. The FSA software can be extracted to text files, which can then be used for data analysis.

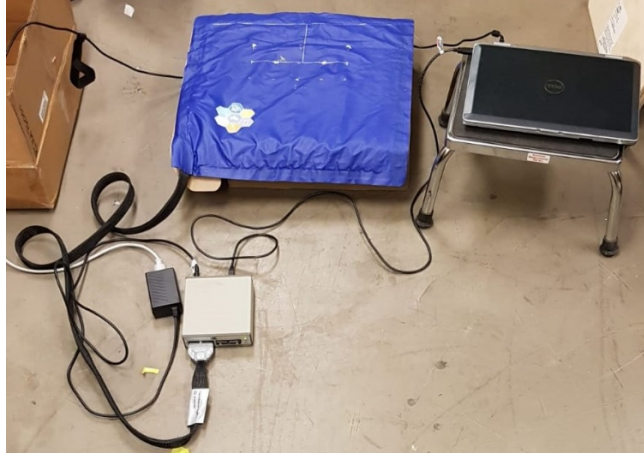


Figure 9. The FSA Pressure Mapping System

7.1.4 Horizontal Stiffness

The horizontal stiffness test characterizes a cushion's ability to absorb horizontal perturbations at the interface between the cushion and the buttocks (International Organization for Standardization, 2018a). The test assumes that high shear stress has an adverse impact on skin integrity. The cushions should make it possible for soft tissue to move and relax without shear strain, thus helping tissue integrity. Higher horizontal stiffness indicates increased postural stability. However, a cushion with high horizontal stiffness may be caused by tissue shear and deformation. The equipment for the horizontal stiffness test consists of a loading rig with an RCLI that can move vertically and horizontally, a digital indicator, and a material testing system with a load cell. The loading rig allows the RCLI to apply a $500\text{N} \pm 10\text{N}$ vertical load to the cushion and assists in lifting the indenter (International Organization for Standardization, 2018a). The digital indicator measures horizontal displacement of the RCLI to provide analog output (Swiss Precision Instruments, Inc., USA). The horizontal force needed to apply a 10 mm horizontal displacement

was measured with a load cell (MTS Systems Corp., USA). This apparatus and setup are depicted in Figure 10.

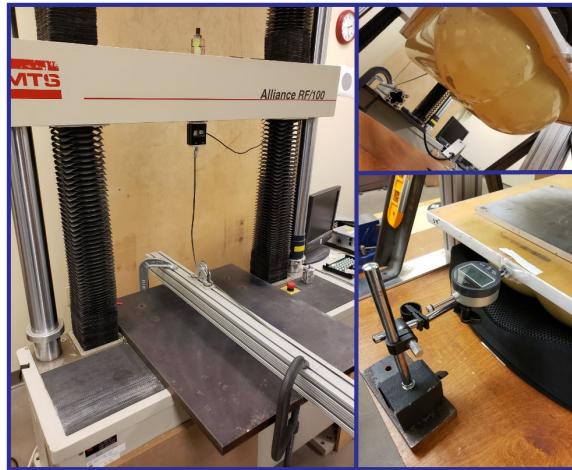


Figure 10. The Apparatus of Horizontal Stiffness Test

7.1.5 Cushion Heat and Vapor Test

The microclimate at the cushion-body interface influences the metabolic and physical properties of the skin and the comfort of wheelchair users (International Organization for Standardization, 2018b). The test method measures heat and water vapor transmission properties of wheelchair cushions under simulated loading conditions (Figure 11). The heat and water vapor dissipating characteristics of seat cushions are related to the material properties at the interface with the skin, which are described as the localized heat and moisture characteristics of the cushions. The test method is measured in steady state condition of the body cushion system (International Organization for Standardization, 2018b).



Figure 11. Measurement System of Heat and Water Vapor Transmission

The measurement system consists of a thermodynamic rigid cushion loading indenter (TRCLI), an external water circulator (NESLAB RTE-110, Artisan Technology Group, USA), a humidifier (MoistAir: HD14070, Essick Air, USA), temperature and humidity sensor (Humiscan, General Eastern, USA), and data acquisition devices (National Instruments cDAQ-9172, NI 9211, NI 9215, USA). To stimulate normal human body conditions for sitting in respect to temperature and water vapor delivery, the TRCLI was used. An external water circulator was used to circulate water to the reservoir of TRCLI, maintaining $35 \pm 2^\circ\text{C}$. A tent was used to maintain the test environment. Ambient temperature was maintained at $23 \pm 2^\circ\text{C}$, and relative ambient humidity was controlled by a humidifier at $50 \pm 5\%$ RH. Ambient climate was monitored by an atmospheric temperature and humidity sensor. The sensor array on the bottom of the outer shell of the TRCLI is made of humidity sensors (Honeywell HIH-4000) and J-type thermocouples. The sensors connected to modules (NI 9211 for thermocouples and NI 9215 for humidity sensors) that were accessed and controlled by a SignalExpress control software (Figure 12) collecting at a 0.2 Hz sample rate. The sensors were placed at several anatomical locations, such as the perineal area, ITs, and thighs, and 500N total load including the TRCLI was applied to the wheelchair cushions

during the test. The cushions were placed in the test environment ($23 \pm 2^{\circ}\text{C}$ and 50 ± 5 RH) for 12 hours before starting the test.

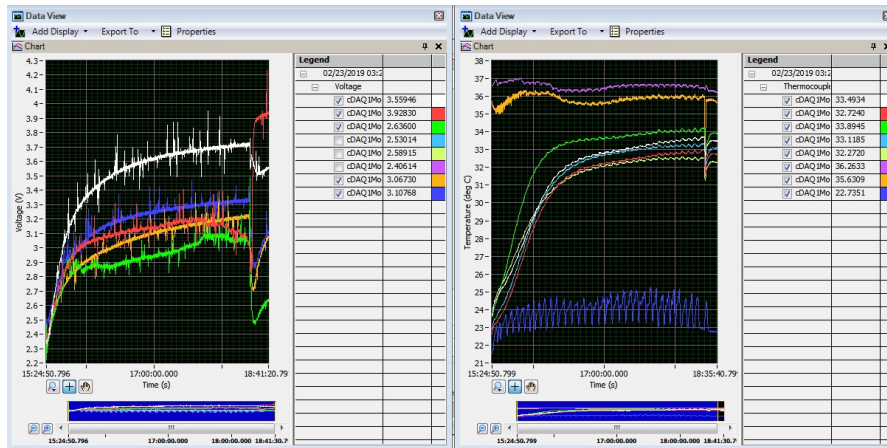


Figure 12. SignalExpress Data Logging – RH Data (Left) and Temperature Data (Right)

7.2 EXPERIMENTAL PROTOCOLS

7.2.1 Load Contoured Depth and Overload Deflection

In this study, each cushion underwent two test sessions with and without the wheelchair cushion cover with microclimate management. Each cushion test required approximately 30 minutes for completion. Prior to conducting the test, each cushion was measured for thickness (Lth). The LCI was placed on the cushion at $125 \text{ mm} \pm 10 \text{ mm}$ forward of the back edge of the cushion (Figure 13). The vertical load of $135\text{N} \pm 5\text{N}$ was applied. After $300\text{s} \pm 10\text{s}$, the vertical height was measured and recorded on the scale (L135). The increase in the vertical load of 45N was added. The vertical distance was measured after $60\text{s} \pm 5\text{s}$ (L180). Lastly, the vertical load was increased to $225\text{N} \pm 5\text{N}$. The final result was recorded on the scale (L225). The test also recorded pass or fail after each trial. The test was conducted three times and had a recovery time of $300\text{s} \pm$

10s between trials. The loaded contour depth (i.e., immersion) was calculated for 135 N load. The two overloaded deflections were calculated as the additional deflection from 135 N to 180 N and 225 N, respectively. The average value of the three trials was used.

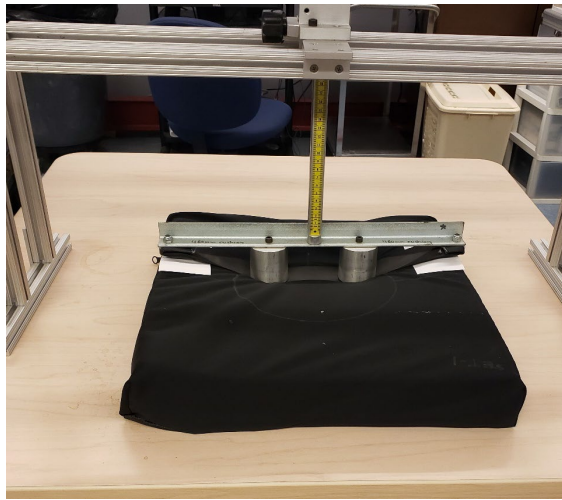


Figure 13. Example of Loaded Contour Dept and Overload Deflection Test

7.2.2 Interface Pressure Measurement

To measure interface pressure, each cushion completed five trials with and without the prototype cover. The test was conducted for approximately 30 minutes over five trials. At least 5 minutes were required to reset the cushion between trials. Prior to this test, the FSA pressure map should be calibrated and adjusted to the system setting on the software. When the test was ready, the cushion was placed under the RCLI with a pressure mat between the RCLI and cushion surface. It was aligned such that the rearmost row of sensors on the pressure mat was aligned with the back edge of the cushion (Figure 14). The interface pressure measurement began recording on the FSA software and the data were collected at a 1 Hz sample rate. The indenter applied on vertical force

of $500\text{N} \pm 10\text{N}$ to the cushion for $60\text{s} \pm 2\text{s}$. The pressure values were recorded in mm Hg corresponding to the 60s of loading and the mean metrics from the five trials used.

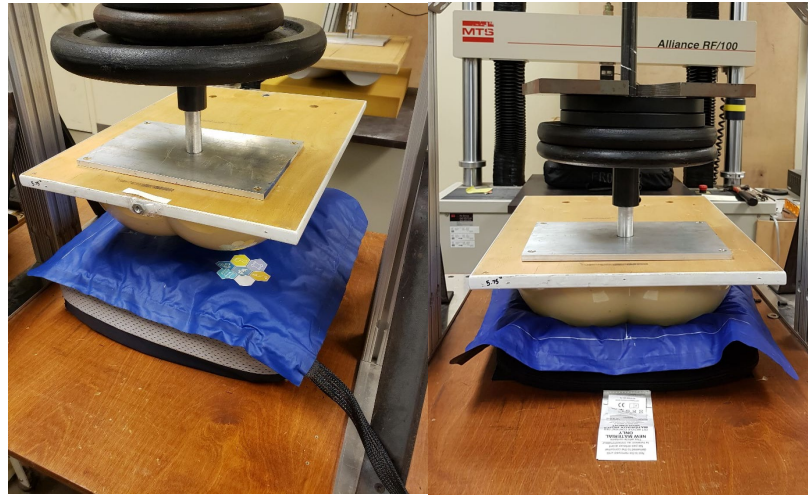


Figure 14. Examples of Interface Pressure Measurement Test

7.2.3 Horizontal Stiffness

For the study, each cushion conducted two testing sessions with and without the prototype wheelchair cover. Each of the three trials included approximately 1 minute for the test session and 10 minutes for cushion reset and a recovery. Per cushion, approximately 35 minutes were required for test completion. The basepoints of the RCLI was aligned with the cushion at $125\text{ mm} \pm 10\text{ mm}$ forward of the back edge of the cushion and applied a total vertical load of $500\text{N} \pm 10\text{N}$. The MTS applied a relative horizontal displacement to the RCLI of $10\text{ mm} \pm 1\text{ mm}$ and maintained the displacement for $60\text{s} \pm 5\text{ s}$ (Figure 15). The pull force was measured by the MTS software, TestWork4, and was recorded in Newtons with a 200 Hz sampling rate. The peak and final horizontal force were recorded and the mean of the three trials used.

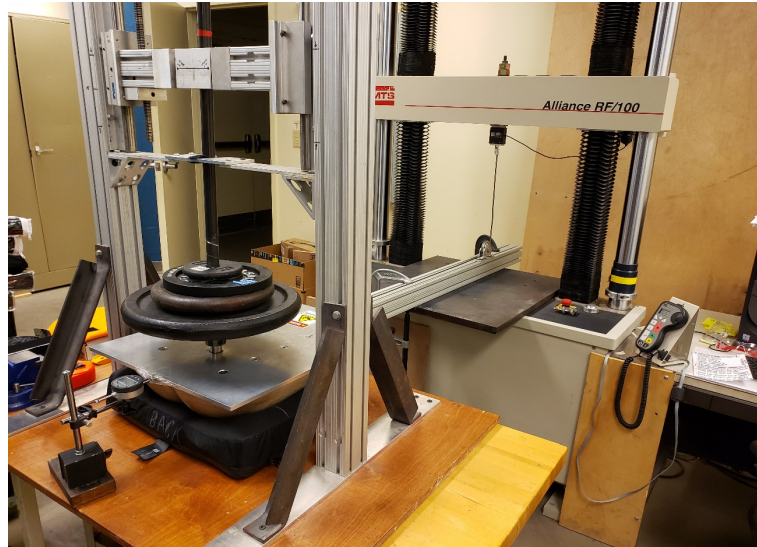


Figure 15. Example of Horizontal Stiffness Test

7.2.4 Cushion Heat and Vapor Test

This comparison used three cushions, with and without the prototype wheelchair cover, and completed six trials. Each trial required 3 hours and 16 minutes to be conducted with simulated loading condition by delivering heat and water vapor (Figure 16). The testing environment of $23\pm 2^{\circ}\text{C}$ and 50% RH was maintained with environmental controls using an external humidifier in the tent. These conditions were verified by a temperature and humidity scanner as well as the onboard sensors of the TRCLI. The water circulator was also maintained between 35°C and 37°C , and 200 ml of distilled water was added to the capillary matting in the TRCLI. Prior to starting the test, the indenter was needed to operate hanging in air in the laboratory environment for at least 1 hour to allow the indenter to reach a thermal steady state. The data recording began with temperature and humidity readings from the sensors at a 0.2 Hz sample rate. The steady state TRCLI was applied onto the cushion when the basepoints of the indenter aligned at $125\text{ mm} \pm 10\text{ mm}$ forward of the back edge of the cushion with a total vertical force of $500\text{ N} \pm 10\text{ N}$. After 180

± 6 minutes, the TRCLI was lifted above the cushion, providing a 100mm ± 20 mm air gaps for 45s ± 10s. The indenter was then returned to the same position on the cushion and the data was recorded by the sensors for 15 minutes. Thereafter, the TRCLI was raised from the cushion and the data collection was terminated. The data recorded included the temperature and humidity at the beginning of the test (T0), 60 minutes (T60), 120 minutes (120), 180 minutes (T180), at the pressure relief lift (T181), and at 196 minutes (T196). The heat and water vapor data were retrieved from SignalExpress and sampled at 6 points throughout each 3 hours trial. The temperature (°C) data were directly generated from SignalExpress via thermocouples, so there was no need to convert the data. However, humidity sensor data were converted from voltage to humidity values using Equation 1:

Equation 1: Conversion of Humidity Sensor Voltage to RH

$$RH = \frac{\left(\frac{Voltage}{5}\right) - 0.16}{0.0062}$$

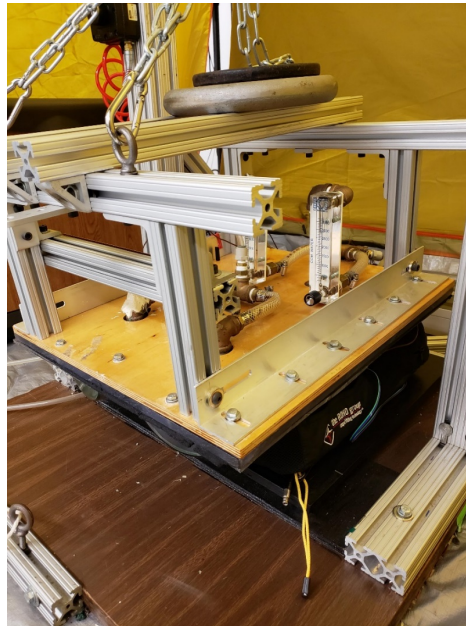


Figure 16. Example of TRCLI Test

7.3 RESULTS

7.3.1 Data Analysis

The analyses for loaded contour depth and overload deflection, interface pressure measurement, horizontal stiffness test, and cushion heat and vapor test were conducted on IBM SPSS Statistics 25 software (Chicago, IL). Prior to comparing cushions with and without prototype cover results, the results had to confirm normal distribution. For the normality test, a Shapiro-Wilk test was chosen since this method is an effective measure of normality for small samples ($n < 20$) (Shapiro & Wilk, 1965). All data was organized in pairs as cushions with and without intervention. The differences between as cushions with and without the prototype were discerned by the normality test using the Shapiro-Wilk test. All data except for the result of L180 overloaded deflection of the pressure mapping test were found to be normally distributed ($p > 0.05$). A paired t-test was used for the normally distributed data, while a Wilcoxon signed rank test was performed for non-parametric distributions, comparing means for generated data for the ISO tests. Both of these test methods were effective for determining the impact of an intervention before and after as a repeated measures design. This study was performed for multiple comparisons. The Bonferroni correction is useful to avoid a single false positive in a set of tests. It is appropriate when there is a fairly small number of multiple comparisons and a study needs to find one or two that might be significant (McDonald, 2014). An adjusted p -value less than 0.002 was regarded as a significant difference.

7.3.2 Loaded Contour Depth and Overload Deflection

The expected results were that the prototype cushion cover should not diminish the wheelchair cushions performance as characterized by the test metrics. The following test results for each cushion compared the values for the loaded contour depth and overloaded deflection between cushions with and without the prototype cover. All values are chosen for the mean of the three trials, as presented in Table 4.

Table 4. The Results of Loaded Contour Depth and Overload Deflection

Cushion	Thickness Lth (mm)	Loaded Contour Depth LCD (mm)	Overload Deflection L180 (mm)	Overload Deflection L225 (mm)
A without Prototype Cover	101.25	61.92	2.33	5.33
B without Prototype Cover	101.25	78.58	4	8.33
C without Prototype Cover	113.92	57.92	4.33	9
Mean (SD)	105.47 (7.31)	66.14 (9.58)	3.56 (1.33)	7.56 (2.07)
A with Prototype Cover	112.25	62.25	2.67	7.67
B with Prototype Cover	110.25	83.25	6	11
C with Prototype Cover	128.58	67.58	5.67	10
Mean (SD)	117.03 (10.06)	71.03 (9.57)	4.78 (1.64)	9.56 (2.35)

There were no significant differences in LCD ($p = 0.008$) and L225 ($p = 0.128$) between before and after intervention (Table 5).

Table 5. Paired Sample *t*-test - Loaded Contour Depth and Overload Deflection between Cushions with and without Prototype Cover

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	SD	Std. Error Mean	99.8% CI of the Difference				
				Lower	Upper			
LCD (mm)	-4.89	4.15	1.38	-11.19	1.35	-3.53	8	.008
L225 (mm)	-2.00	3.54	1.18	-7.30	3.30	-1.70	8	.128

There was no significant difference in L180 ($p = 0.014$) between cushions with and without the prototype cover (Table 6).

Table 6. Wilcoxon Signed Test – L180 between Cushions with and without Prototype Cover

	Z	Asymp. Sig. (2-tailed)
L180 (mm)	-2.456 ^a	.014

a. Based on negative ranks.

7.3.3 Interface Pressure Measurement

To analyze the results of this test, the data were divided into zones related to the anatomy. The base point zones (BPZ) corresponding to the ischial tuberosities were defined as 110 mm wide by 110 mm, each centered 130mm forward of the rear of the cushion and 55mm lateral to the centerline. The BPZ was divided into the right base zone (RBZ) and the left base zone (LBZ). The rear center zone (CZ) make up the area behind BPZ and corresponds to the sacral-coccyx region. The Peak Pressure Index (PPI) was defined in BPZ were calculated by the greatest sum of pressures in the a 9-10 cm² area (Sprigle et al., 2003). Dispersion index was calculated from the sum of the pressure readings in RBZ, LBZ, and CZ divided by the sum of all pressure reading. The contact area was defined as the area of pressure readings, whose values were 5 mm Hg or greater.

The test results for each cushion and data analysis indicate PPI, Dispersion Index, and Contact Area as presented in Table 7 and Table 8. All values are averages of five trials.

Table 7. The Results of Interface Pressure Measurement –PPI, Dispersion Index, and Contact Area

Cushion	PPI in RBZ (mm Hg)	PPI in LBZ (mm Hg)	Dispersion Index (%)	Contact Area (mm ²)
A without Prototype Cover	57	44	23.19	90837.24
B without Prototype Cover	79	99	36.88	124226.85
C without Prototype Cover	67	55	54.31	78735.33
Mean (SD)	66 (11)	66 (29)	38.13 (13.31)	97933.14 (23561.27)
A with Prototype Cover	42	39	18.15	91857.88
B with Prototype Cover	77	89	33.62	122185.56
C with Prototype Cover	49	47	58.15	87337.89
Mean (SD)	56 (18)	58 (27)	36.64 (17.12)	100460.44 (18949.75)

There were significant differences in the PPI of RBZ ($p = 0.001$) and LBZ ($p = 0.000$) between cushions with and without the prototype. There were no significant differences in Dispersion Index ($p = 0.242$) and Contact Area ($p = 0.101$) between before and after intervention.

Table 8. Paired Sample *t*-test - PPI, Dispersion Index, and Contact Area between Cushions with and without Prototype Cover

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	SD	Std. Error Mean	99.8% CI of the Difference				
				Lower	Upper			
PPI vs RBZ	10.09	9.63	2.49	0.86	19.51	4.06	14	.001
PPI vs LBZ	8.05	4.67	1.21	3.47	12.62	6.67	14	.000
Dispersion index (%)	1.49	4.72	1.22	-3.13	6.10	1.22	14	.242
Contact Area (mm ²)	-2527.31	5578.51	1440.36	-7982.53	2927.92	-1.76	14	.101

7.3.4 Horizontal Stiffness

The peak horizontal force (N) was calculated as the average of the loads (N) while maintaining the displacement at $60s \pm 5s$. The final horizontal force (N) was recorded as the values of the end of the test. The results and data analysis of horizontal stiffness test are presented in Table 9.

Table 9. The Results of Horizontal Stiffness Test

Cushion	Peak Horizontal Force (N) Mean (SD)	Final Horizontal Force (N) Mean (SD)
A without Prototype Cover	127.97 (13.96)	99.85 (14.82)
B without Prototype Cover	70.89 (4.17)	57.75 (5.06)
C without Prototype Cover	145.81 (17.35)	108.95 (18.08)
Mean (SD)	114.89 (35.73)	88.85 (26.51)
A with Prototype Cover	81.74 (24.25)	56.30 (20.30)
B with Prototype Cover	64.00 (3.14)	50.03 (3.11)
C with Prototype Cover	101.65 (7.69)	72.74 (7.17)
Mean (SD)	82.46 (20.83)	59.69 (14.88)

The differences in peak horizontal force ($p = 0.009$) and final horizontal force ($p = 0.010$) between the cushions were not significant with and without the prototype cover (Table 10).

**Table 10. Paired Sample *t*-test – Horizontal Stiffness Test
between Cushions with and without Prototype Cover**

	Paired Differences					t	df	Sig (2-tailed)
	Mean	SD	Std. Error Mean	99.8% CI of the Difference				
				Lower	Upper			
Horizontal Force (N)	32.43	28.58	9.53	-10.46	75.31	3.40	8	.009
Horizontal Force (N)	29.16	25.90	8.63	-9.69	68.02	3.38	8	.010

7.3.5 Cushion Heat and Vapor Test

When collecting data for one cushion, a problem occurred since the humidity sensors were wet due to the moisture from the TRCLI. Therefore, one trial of the cushion was used with three sensor readings instead of five sensor readings. The results of water vapor and data analysis are provided in Table 11.

Table 11. The Results of Relative Humidity

Cushion	T0 (%)	T60 (%)	T120 (%)	T180 (%)	T181 (%)	T196 (%)
A without Prototype Cover	46.28 (0.10)	70.25 (3.40)	77.22 (3.56)	79.41 (3.12)	68.33 (4.69)	74.83 (4.59)
B without Prototype Cover	52.60 (2.26)	73.73 (1.15)	76.83 (2.14)	78.00 (2.02)	69.86 (3.61)	74.06 (3.17)
C without Prototype Cover	46.58 (2.57)	69.44 (2.00)	74.68 (1.90)	78.29 (1.83)	70.08 (0.05)	74.24 (1.48)
Mean (SD)	48.39 (3.81)	71.18 (3.29)	76.16 (3.18)	78.48 (2.77)	69.94 (4.09)	74.95 (4.21)
A with Prototype Cover	47.30 (0.63)	50.97 (0.70)	50.88 (0.69)	49.46 (1.25)	44.37 (1.56)	48.27 (2.68)
B with Prototype Cover	50.60 (0.69)	49.63 (0.72)	46.95 (0.90)	47.60 (1.46)	44.47 (1.73)	46.01 (1.30)
C with Prototype Cover	47.45 (1.21)	48.31 (0.82)	45.88 (0.87)	45.87 (1.19)	42.51 (0.93)	47.38 (1.46)
Mean (SD)	48.45 (1.87)	49.64 (1.47)	47.90 (2.49)	47.64 (2.23)	43.78 (2.01)	47.24 (2.53)

There were significant differences in relative humidity for the entire test session ($p = 0.000$, 0.000, 0.000, 0.000, and 0.000 for T60, T120, T180, T181, and T196 respectively) except for T0 ($p = .957$) (Table 12).

Table 12. Paired Sample *t*-test – Relative Humidity between Cushions with and without Prototype Cover

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	SD	Std. Error Mean	99.8% CI of the Difference				
				Lower	Upper			
T0 (%)	-0.06	3.20	1.07	-4.87	4.75	-0.06	8	.957
T60 (%)	21.55	3.65	1.22	16.07	27.02	17.71	8	.000
T120 (%)	28.25	3.55	1.18	27.93	33.58	23.87	8	.000
T180 (%)	30.83	3.17	1.06	26.08	35.59	29.21	8	.000
T181 (%)	26.16	4.58	1.53	19.28	33.04	17.12	8	.000
T196 (%)	27.72	5.46	1.82	19.52	35.91	15.23	8	.000

The average temperature values are shown in Table 13. The 2-tailed paired sample *t*-test was conducted using the two sets of temperature obtained from cushion heat and vapor test.

Table 13. The Results of Temperature

Cushion	T0 (°C)	T60 (°C)	T120 (°C)	T180 (°C)	T181 (°C)	T196 (°C)
A without Prototype Cover	26.65 (0.22)	32.16 (0.26)	33.57 (0.41)	33.98 (0.60)	31.23 (0.08)	33.95 (0.76)
B without Prototype Cover	23.37 (0.32)	31.08 (0.63)	33.03 (0.48)	32.95 (0.34)	32.27 (0.15)	32.71 (0.30)
C without Prototype Cover	26.47 (1.29)	32.88 (0.23)	33.26 (0.61)	33.39 (0.74)	31.40 (0.64)	33.21 (0.79)
Mean (SD)	25.52 (1.81)	32.08 (0.91)	33.26 (0.56)	33.40 (0.71)	31.71 (0.62)	33.19 (0.80)
A with Prototype Cover	27.20 (0.85)	32.01 (0.25)	32.71 (0.23)	32.93 (0.25)	30.89 (0.11)	32.67 (0.33)
B with Prototype Cover	24.14 (0.80)	31.32 (0.34)	32.56 (0.17)	32.61 (0.10)	31.73 (1.12)	32.47 (0.23)
C with Prototype Cover	26.49 (0.81)	32.59 (0.44)	32.67 (0.16)	32.50 (0.21)	30.05 (0.63)	32.32 (0.33)
Mean (SD)	25.94 (1.64)	31.97 (0.67)	32.65 (0.21)	32.68 (0.29)	30.89 (1.07)	32.49 (0.35)

The test results were not statistically significant differences in temperature for the entire test session ($p = 0.411, 0.675, 0.016, 0.017, 0.022, 0.047$ for T0, T60, T120, T180, T181, and T196 respectively). (Table 14).

Table 14. Paired Sample *t*-test – Temperature between Cushions with and without Prototype Cover

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	SD	Std. Error Mean	99.8% CI of the Difference				
				Lower	Upper			
T0 (°C)	-0.43	1.47	0.49	-2.63	1.78	-0.87	8	.411
T60 (°C)	0.11	0.73	0.24	-0.99	1.21	0.44	8	.675
T120 (°C)	0.61	0.60	0.20	-0.30	1.51	3.03	8	.016
T180 (°C)	0.73	0.73	0.24	-0.36	1.82	3.00	8	.017
T181 (°C)	0.82	0.87	0.29	-0.49	2.12	2.82	8	.022
T196 (°C)	0.70	0.90	0.30	-0.65	2.06	2.34	8	.047

All data were displayed in Figure 17 and Figure 18 to illustrate the high repeatability between cushions trials

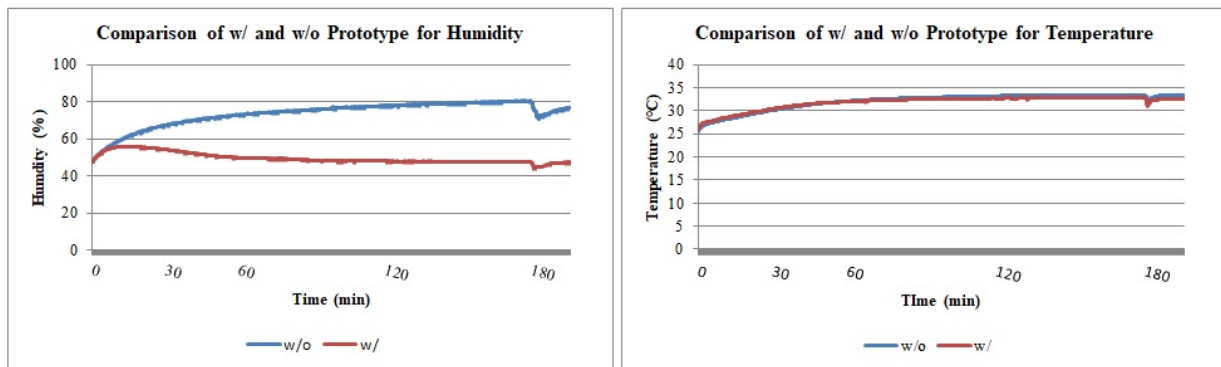


Figure 17. Average Values for Cushions with and without Prototype

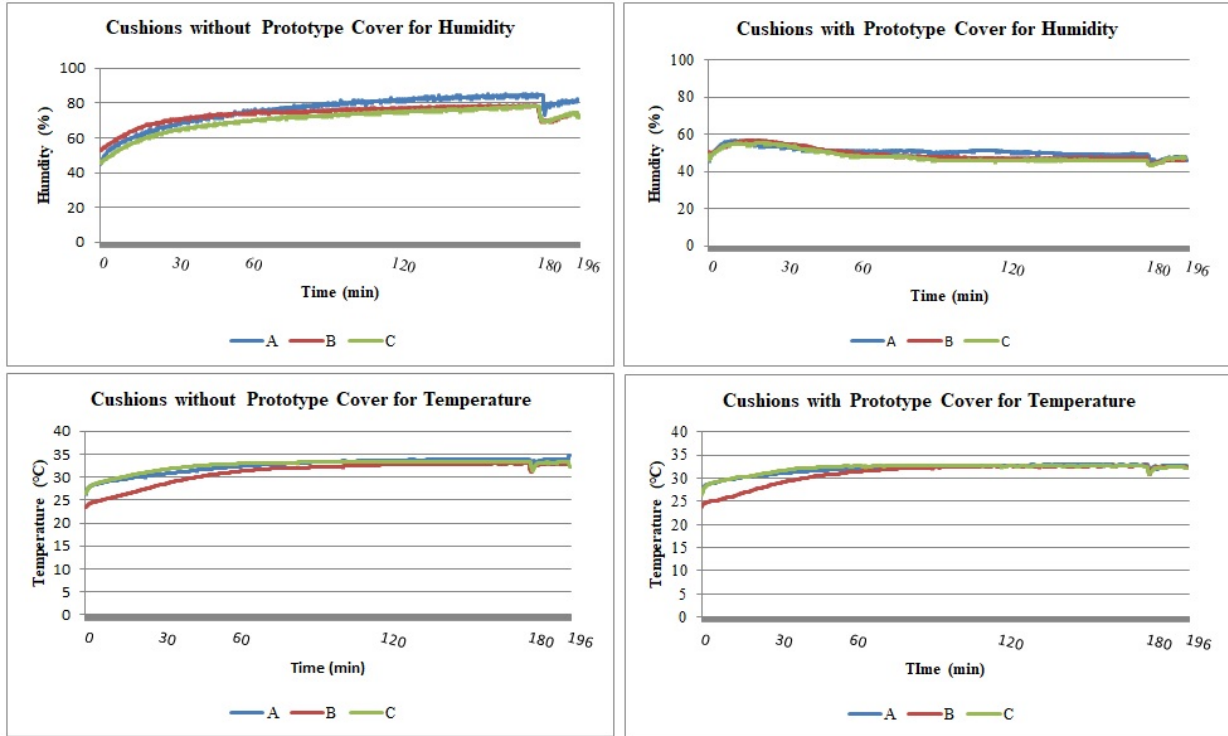


Figure 18. Average Values for Each Cushion with and without Prototype

7.4 DISCUSSION

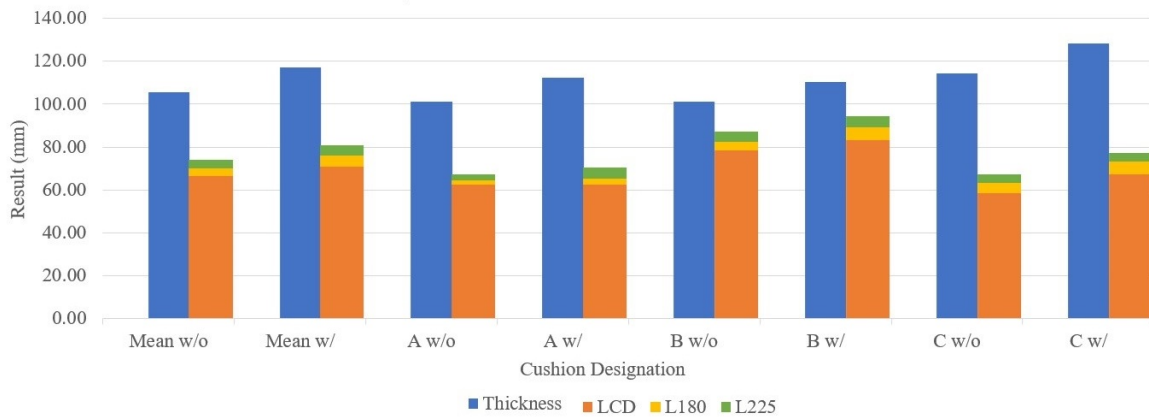
7.4.1 Loaded Contour Depth and Overload Deflection

Identifying the immersion capacity is a simple way to determine the cushion characteristics. The results of the loaded contour depth and overload deflection are important because the test can be used by the CMS to characterize cushions and give them a code designation. This result determines insurance coverage in the CMS HCPCS (*Local Coverage Article : Wheelchair Seating - Policy Article (A52505)*, 2019).

Based on ISO 16840-2, Annex B, the expected ranges of the test results are 10–90 mm for LCD, 0–15 mm for L180, and 0-10 for L225. All cushions passed without bottoming out. The

expected result for this test was that the prototype cover would not diminish the cushion's characteristic of immersion. When comparing the results for the cushion with and without the prototype cover, cushions without the prototype demonstrated values within the expected ranges of the ISO test, and cushions with the cover indicated that all values increased, as detailed in Figure 19,

Figure 19. Comparison of Results of LCD and Overload Deflection



The cushion thickness was increased by approximately 10 mm. This result explains the prototype cover's additional enveloping of the cushion, which contributed to an increase in cushion thicknesses due to the spacer material between the outer and inner layers of the prototype cover. The values of the results of LCD, L180, and L225 increased as the cushion thicknesses increased.

Given the statistic results, no significant differences were found in LCD ($p = 0.008$), L180 ($p = 0.128$) and L225 ($p = 0.014$) between cushions with and without the prototype cover. Therefore, the result of the loaded contour depth and overload deflection reveal the prototype cover did not negatively influence the cushions' performance with regard to pressure reduction.

7.4.2 Interface Pressure Measurement

With respect to the cushion's pressure distribution characteristics, one challenge was the microclimate management aspect of cushion cover design. To improve microclimate conditions during sitting, the intervention could not interfere with the cushion's capacity to distribute pressure at the interface. If the prototype cover increased the pressure point at the interface, the device would be useless as pressure is the primary factor in pressure injury (Pieper, 2015).

A statistically significant decrease was observed between the cushions with and without the prototype cover at the area of RBZ and LBZ. More specifically, the cushion with the prototype cover provided additional pressure distribution. Two factors might have led to this additional pressure distribution. One factor is the design of the cover to avoid the hammock effect. Unlike other wheelchair cushion covers, the prototype cover was designed to accommodate a curved surface at each lateral side. This might reduce tension from the curved layer and thus avoid radial pressure. As a result, the RBZ and LBZ might be measured with less pressure. However, it is hard to detect the hammock effect using current pressure mapping techniques (Morita et al., 2012). Therefore, it is difficult to determine whether the pressure reduction was caused by the reduction of the hammock effect since the difference of the zone force in the pressure mat readings between the cushions with and without the prototype cover was visually discernable, as depicted in Figure 20.

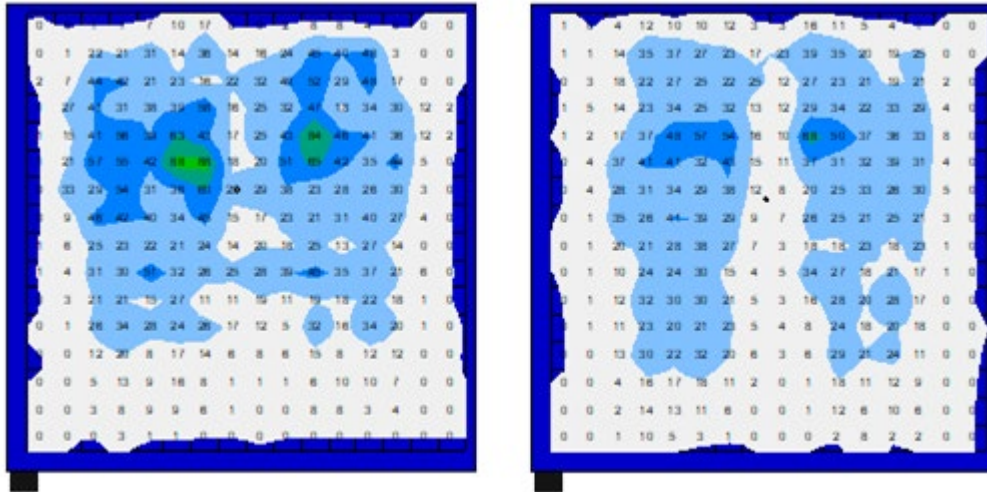


Figure 20. Pressure Mat Reading Examples: (Left) Cushion without Prototype and (Right) Cushion with Prototype

Another factor of the additional pressure distribution was the spacer material, which could have provided additional pressure distribution. The spacer material was designed to reduce pressure distribution for bedsores or pressure sores. The spacer material was assessed by a pressure measurement test that compared the spacer material with Polyurethane (PU) foam. The spacer material more efficiently reduced pressure concentration than PU foams. Thus, the spacer material is useful for special applications, such as relief of body pressure (Xiaohua et al., 2008). Furthermore, the mattress with spacer fabric demonstrated better results on the pressure measurement test than the mattress without spacer fabric (Xiaohua et al., 2008). Future studies should investigate the relationship between spacer material and pressure distribution in wheelchair cushions.

According to ISO 16840-6:2015, in order for the test results to be valid, the total force had to fall within $\pm 10\%$ of the force applied to the seat cushion by the indenter. The results of the total force reveal 398.23N for the cushions without the prototype cover and 371.15N for the cushions with the prototype cover. Therefore, the pressure magnitude results may be invalid because the total force was not within $500\text{N} \pm 10\%$. However, the results were still valuable to perform a

relative comparison between cushions with and without the prototype cover. Additionally, Sprigle et al. (2003) have explained that the load calculated from the recorded pressure values does not always meet the requirement. This could be attributed to the contouring of the cushion under load, such that the increased contouring leads to mapping senses rotated off the line of gravity and, thus, the off-axis loading causes an error (Sprigle et al., 2003). For more accurate comparisons, future studies should be conducted using this test and include the test requirements of the total force.

7.4.3 Horizontal Stiffness

Shear is the result of interplay between gravity and friction. It generates a force parallel to the skin and is caused by gravity pushing down on the body as well as resistance (Pieper, 2015). Horizontal stiffness indicates that a cushion may offer more tissue deformation and shear while also increasing stability. In contrast, low horizontal stiffness may decrease stability but reduce tissue deformation and shear force (International Organization for Standardization, 2018a). ISO 16480-2, Annex B has noted the expected range of results for the horizontal stiffness as 48N – 168N in 5 mm horizontal displacement. However, this study was performed for the measurement of 10 mm horizontal displacement. As such, no comparison has been made between the expected data and the test results. Moreover, horizontal stiffness from this test method may be a poor indication of interface shear at ischial tuberosities. Akins, Karg, and Brienza (2008) followed a similar methodology to ISO 16480-2, Annex C in order to determine horizontal stiffness and additionally measured interface shear stress. The results of their study questioned the value of the ISO test for horizontal stiffness to measure interface shear. In 2011, a large follow-up study reported a correlation between ISO 16480-2, Annex C and the overall stiffness results of their

study. Yet, the horizontal stiffness test did not provide information about the interface shear stress of the cushion (Akins, Karg, & Brienza, 2011).

No significant differences were noted in the peak and final horizontal force between cushions with and without the prototype cover ($p = 0.009$ and $p = 0.010$), though the peak and final force decreased with the prototype cover. The prototype cover did not have a negative influence on the stability of the cushions in terms of tissue deformation and shear force.

7.4.4 Cushion Heat and Vapor Test

Ferguson-Pell et al. (2010) have conducted comparisons of the wheelchair cushions used to TRCLI to deliver controlled heat and water vapor. In their case, 32 commercially available cushions were tested. The results of the study revealed a strong correlation between temperature and core material. A weak significant difference was observed for moisture, which correlated with core material. The results of the air cushion were compared to the measurements of this study for cushion B, with and without the prototype cover. (Table 15) The results of air from the Ferguson-Pell study indicated higher values of temperature and lower values of humidity than the results of cushion B. However, these differences are not significant. For cushion B with the prototype cover, the values of humidity reveal a discernible difference at H1 and H2. The cushion with the prototype shows 12.37% and 18.45% average drops when compared to the results of the literature at H1 and H2. While the values for temperature and humidity of the cushion without the prototype and the values reported from the literature all increased over time, the values for cushion B with the prototype decreased in terms of humidity. Based on their classification system, the air cushion was listed as a low moisture dissipater ($H1 > 60\% RH$). The prototype cover would facilitate the

cushion’s ability to dissipate moisture at the interface given that the results of cushion B with the prototype cover were below 50% RH.

Table 15. Comparison of Results for Ferguson-Pell et al. and Our Study

Cushion	Direct Measurement				
	T1 (°C)	H1 (%)	T2 (°C)	H2 (%)	T1-0 (°C)
Ferguson-Pell (Air Cushion)	35.20	62.00	35.50	65.40	4.50
B without prototype cover	31.08	73.73	33.03	76.83	7.71
B with prototype cover	31.32	49.63	32.56	46.95	7.18
	Difference Measure				
	H1-0 (%)	T2-1(°C)	H2-1 (%)	T2-0 (°C)	H2-0 (%)
Ferguson-Pell (Air)	19.80	0.30	3.30	4.80	23.20
B without prototype cover	21.13	1.95	3.10	9.66	24.23
B with prototype cover	-0.98	1.24	-2.68	8.42	-3.66

More recently, Hsu et al. (2018) have studied the real-time measurement for temperature and humidity at the body-seat interface. Their study used a 2-hour continuous sitting protocol and placed four sensors under the participants’ ITs and thigh, bilaterally. The test results indicate that the wheelchair cushions do not significantly decrease moisture at the body-seat interface. The results of the air-filled rubber cushion were comparable to those of this study. The results for temperature from their study and the present study were also similarly measured, although the level of humidity in the real-time measurement was higher than in the TRCLI test (Table 16). Compared to the literature values, cushion B with the prototype cover provides a better environment at the surface interface for real-world situations.

Table 16. Comparisons of the Results between Hsu et al. and Our Study

Cushion	T120 (°C)	H120 (%)
Hsu et al. (Air Cushion)	34.7	89.6
B without prototype cover	33.03	76.83
B with prototype cover	32.56	46.95

Given the TRCLI test results, the humidity level of cushions with the prototype cover was lower than that of the cushions without the cover. The values of the results maintained approximately 50% humidity and reported a significant decrease across all datasets (T60, T120, T180, T181, and T196), except for the beginning of the test (TO). The optimal microclimate at skin surface is currently unknown (NPUAP, 2014). However, as mentioned in Section 2.2.3, SC hydration plays significant roles in tissue properties. Imhof et al. (2009) have explained that the stable status of the SC ranges from 40% to 60% RH and that SC hydration is accelerated over 60% of RH. Therefore, maintaining a humidity level around 50% is reliable for pressure injury prevention. In addition, the results which maintain 50% of RH might be linked to the ambient RH because water vapor was absorbed to the support surface layer, diffused to the airway of the spacer material, and then exchanged with moisture between the high RH of inside air and the low RH of outside air. Therefore, it is maintained at RH that matches the humidity level of outside air. Future studies should investigate the measurement of RH at the support interface in different humidity environments since high and low RH at the interface may negatively affect skin properties.

Local cooling prevents the formation of pressure injury, as explained by the lab-based animal studies (Iaizzo et al., 1995; Lachenbruch, 2005). However, this study indicates that the prototype cover did not help cushions dissipate heat at the interface over the entire test session. Local cooling suggests that maintaining a temperature of 25°C may have a protective effect (Kokate et al., 1995). Compared to the ability of decreasing moisture at the surface interface, the ability to reduce temperature was insufficient. Future studies should modify the cushion in order to increase the function of reducing temperature at the surface interface.

8.0 FOCUS GROUP EVALUATION

8.1 FOCUS GROUP METHODS

A group of clinicians were individually interviewed in order to evaluate the wheelchair cushion cover with microclimate management and its design criteria.

8.1.1 Recruitment

The rehabilitation professionals, including occupational therapists and physical therapists, were recruited for the interviews. All five clinicians are involved in the wheelchair prescription. All participants were individually contacted and agreed to make appointments for the interview.

8.1.2 Protocol

This study did not required approval by the University of Pittsburgh Institutional Review Board since it was an interviews of rehabilitation professionals. The participants received an oral introduction to the prototype wheelchair cushion cover with microclimate management. Its functions and operation were demonstrated. The participants were asked to test the prototype and were encouraged to sit on the wheelchair cushion with the prototype cover. After finishing the trial and discussion, participants were asked to complete a questionnaire to evaluate the prototype.

8.1.3 Questionnaire

The questionnaire was designed to ask participants for feedback about the prototype's operation, function, and appearance. The questionnaire used a 5-point Likert scale. Participants were asked to mark an X at one of the points in order to indicate their opinion. The scale represents participant preference for the question, ranging from strongly disagree to disagree, neutral, agree, and strongly agree. If participants chose strongly disagree, disagree, or neutral, they were asked to note the reason for their choice. Open-ended questions were also included related to the strength and weakness of the prototype.

8.1.4 Data Analysis

The questions answered using a 5-point Likert scale were analyzed using SPSS 25.0 (IBM, Chicago, IL). The results of the 5-point scale were converted to a scale of 100, where 100 reflects strongly agree, 50 represents neutral, and 0 means strongly disagree. Eight features of the wheelchair cover with microclimate management were evaluated. The mean scores of each of the eight features were calculated.

8.2 EVALUATION

8.2.1 Participant

The clinician group was comprised of two physical therapists and three occupational therapists. The mean experience of the group was 17.5 years (Table 17). All clinicians were involved in the wheelchair prescription.

Table 17. Information of the Clinician Group

ID	Professionals	Experience (year)
01	Occupational therapist	30
02	Occupational therapist	10
03	Occupational therapist	1.5
04	Physical therapist	21
05	Physical therapist	25

8.2.2 Evaluation of Wheelchair Cushion Cover with Microclimate Management

8.2.2.1 Quantitative Results

Table 18 details the questionnaire results by categories. The average scores ranged from 50 to 95. Ratings over 90 were received in three categories: compatibility (95 ± 11.18), noise (95 ± 11.18), and appearance (90 ± 13.69). Four categories scored between 70 and 90: size (80 ± 20.91), simplicity (80 ± 11.18), comfort (70 ± 11.18), and functionality (85 ± 13.69). The lowest rating was received in washing (50 ± 17.68). The overall mean rating for all categories was 82 ± 5.59 .

Table 18. The Results of Questionnaire by Categories

Category	N	Mean	SD
Size	5	80	20.92
Simplicity	5	80	11.18
Compatibility	5	95	11.18
Comfort	5	70	11.18
Functionality	5	85	13.69
Noise	5	95	11.18
Washing	5	50	17.68
Appearance	5	90	13.69
Overall	5	82	5.59

Most categories received ratings greater 70 as shown in Figure 21. The participants agreed with the compatibility of the prototype cover with commercially available cushions. Overall, the participants answered that the wheelchair cushion cover with microclimate management met the design criteria

Figure 21. Average of Ratings by Categories

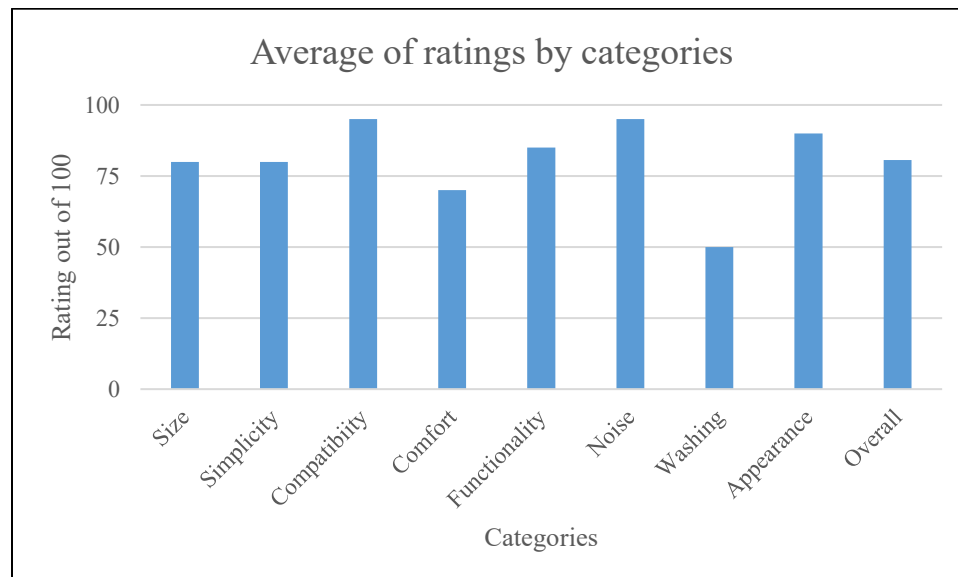


Table 19 displays the questionnaire results organized by participant. Three participants gave ratings over 80. Two clinicians rated the prototype cover greater than 70. The results by participants were consistent.

Table 19. The Results of Questionnaire by Participants

ID	Overall Mean	SD
1	71.88	8.84
2	78.13	20.86
3	84.38	18.60
4	84.38	18.60
5	84.38	26.52

All participants agreed with that would be recommend the prototype to their clients if the cover were to be commercially available. Two participants chose over \$200 as a reasonable price. One clinician selected the price range as \$100–\$150. Two participants preferred an inexpensive price for the cover, from \$50 to \$100 (Table 20).

Table 20 Expected Price

Price	N
\$10 ~ \$50	
\$50 ~ \$100	2
\$100 ~ \$150	1
\$150 ~ \$200	
More than \$200	2

8.2.2.2 Qualitative Results

The participants suggested the cover with microclimate management would offer positive benefits for wheelchair users. All participants agreed with the concept for the prototype cover, which helps reduce temperature and moisture at the seat interface. However, one participant suggested the prototype cover needed to undergo clinical experiments with wheelchair users to prove clinical effectiveness. One participant proposed that a fan under the buttock, similar to the one at the back of the cushion, would further help ventilation. What all participants liked most about the cover was that the design appeared compact and the fan was quiet when the system operated. Moreover, the cover was lightweight and fit over currently available wheelchair cushions. What all participants disliked most about the cover was that it appeared that it would be difficult for the cover to be washed and cleaned and thus manage incontinence. As the current design needed to be plugged into an outlet, this function restricts the use of the cover. The increased size would negatively affect the size of the cushion when in the wheelchair. It was suggested that it may be difficult to maintain the cover if users are not compliant with care instructions. The recommendation for the improvement was that the device use a battery pack for operation in order to be used anywhere. It was also suggested that the current design of the cover had too many layers and needed to be simpler and more compact.

8.3 Discussion

All participants agreed with the concept and necessity of the product, which manages the microclimate at the body-seat interface. The overall mean of ratings was 82 ± 5.59 . These results suggest that the participants agreed and strongly agreed with the positive statements about the

cover and its operation, which are favorable responses. In general, the agreement conveyed to the statements on the questionnaire imply that the participants are supportive idea that this product serves a need for pressure injury prevention and that it would be an important commercial development. The focus group gave the highest rating on the compatibility category. As the noise of the fan during the operation was quiet, this category also received the highest rating. This was an important criterion for the user because the user may stop using the cover due to the noise. However, a significant perceived problem pointed out by the focus group was that it would be difficult to wash. Since the upper part of the cover is not removable, it is not possible to clean and wash the inner cover or spacer material, which could become contaminated by moisture, urinary or fecal incontinence, and wound drainage. This problem should be solved by modifying the cover design for the next prototype. Moreover, it remains unclear as to whether urinary or fecal incontinence could be absorbed into the airway and might cause odor problems through the fan. Future studies should investigate odor due to contamination of urinary or fecal incontinence.

9.0 LIMITATIONS

One of the primary challenges in the data collection of TRCLI was capturing the humidity at the interface with the J3 cushion when tested without the prototype cover. This limitation resulted from the fact that the J3 cushion was a hybrid style, which combined viscous fluid and contoured elastic foam. Under a simulated loading condition with TRCLI, the buttocks area of the J3 cushion was floating due to the off-loading design. As such, moisture supplied from the indenter collected at the surface of the indenter, which caused the sensor to get wet (100% RH). Since the sensor output is only valid below 100% RH several trials were invalidated and valid data could only be recorded for one trial for J3 cushion in which data from the three sensors were usable.

In addition, this research faced a limitation in maintaining a test environment for TRCLI. At the time of the experiment, the laboratory environment was dry. Therefore, in order to control the environment, a tent was used with a humidifier installed. The standard specifies that the test environment be maintained at $23\pm 2^{\circ}\text{C}$ and $50\%\pm 5\%$ RH. The temperature was maintained for the experimental environment. However, when the humidifier was used in a small space, the environment slightly deviated from $50\% \pm 5\%$ RH.

The methods for evaluating the prototype also limited the strength of the outcome. This study was conducted using a lab-based test and a focus group evaluation with rehabilitation professionals. A wheelchair user test and an evaluation of the wheelchair users' opinion were not performed. This study also did not evaluate performance in real life conditions where problems such as clogged fan by the cover and heat during fan operation might affect performance.

Moreover, temperature and humidity were not measured by engaging wheelchair users. Focus group evaluations of wheelchair users were not implemented.

This study examined the validity of the prototype cover using three wheelchair cushions. The test results of the prototype demonstrated sufficient performance with those three wheelchair cushions. However, many more types of wheelchair cushions are available on the market. With only three wheelchair cushions tested, the positive performance observed cannot be generalized to all cushions.

Lastly, the use of interface pressure measurement as an outcome measure is a limitation. To validate data from the interface pressure measurement tests, the total force calculated by the pressure should have been within $\pm 10\%$ of the 500N applied. However, the total force was outside of that range (consistently lower) therefore, did not meet the ISO test requirement for a valid test.

10.0 FUTURE DIRECTIONS

The wheelchair cushion cover with microclimate management was equipped with a fan operated by at 110 VAC. Future generations of this design should implement a cover whose fan is operated by a battery pack, which is rechargeable by connecting to USB. This feature would enable the user to operate the cover in without the need to plug into AC power.

The cover should be modified to improve temperature management. Although the current design reduced humidity, it was insufficient in reducing temperature at the seat interface. In order to achieve this design goal, the spacer material should be modified at the specific site where local cooling is needed by using gel pad materials with high thermal conductivities. The negative flow from the fan would enable the gel pad cooling effects to help the specific site reduce temperature. In addition, the cover should be tested with more wheelchair cushions in order to generalize the function of microclimate management.

Human subject testing should be performed to evaluate the cover and its microclimate management capability. An instrument should be developed to measure humidity and temperature at the surface interface in real time for the human subject test. Instead of the TRCLI test, the modified test should provide valuable data at the seat interface with the wheelchair cushions, with and without the cover. Future studies should utilize these real-time measurements for temperature and humidity at the body-seat interface.

Finally, a focus group evaluation should be held for wheelchair users. The evaluation should include quantitative and qualitative data in order to evaluate the pros and cons of the cover. This data could improve the design of the next generation of the cover and resolve more of the current design's problems.

11.0 CONCLUSIONS

The results of this study demonstrate that the wheelchair cushion cover with microclimate management effectively controls moisture at its top surface in the range near 50% RH. In a simulated loading condition using a TRCLI, our system was able to control moisture at the surface interface when given a constant heat and water vapor load for a 3-hour duration. The cover with microclimate management provided significantly decreased interface humidity compared to the same cushions without our system.

The wheelchair cushion cover with microclimate control combines features of currently available wheelchair cushions with effective humidity management. The cover was evaluated with standard performance tests for loaded contour depth and overload deflection, interface pressure measurement, and horizontal stiffness in order to evaluate the characteristics of the cover combined with the cushions. The test results indicate that the cover provides additional pressure distribution and did not negatively influence the cushion's mechanical load bearing characteristics.

In the focus group evaluation of our system, all participants agreed that our system would provide valuable features when added to current cushion interventions. Our system received an overall positive response from participants. All participants agreed with the utility of microclimate management features and confirmed the necessity of the product. They would recommend the cover to wheelchair users.

Appendix A

All data of each cushion for loaded contour depth and overload deflection, interface pressure measurement, horizontal stiffness test, and cushion heat and water vapor test.

A.1 Loaded Contour Depth and Overload Deflection

J3

w/o	Thickness (mm)	L135 (mm)	L180 (mm)	L225 (mm)
Trial 1	101.25	62.25	2	5
Trial 2	101.25	61.25	2	5
Trial 3	101.25	62.25	3	6
Mean	101.25	62.92	2.33	5.33
w/	Thickness	L135	L180	L225
Trial 1	112.25	62.25	3	8
Trial 2	112.25	62.25	2	5
Trial 3	112.25	62.25	3	10
Mean	112.25	6	2.67	7.67

ROHO Quadtro Select High Profile

w/o	Thickness (mm)	L135 (mm)	L180 (mm)	L225 (mm)
Trial 1	101.25	80.25	2	6
Trial 2	101.25	77.25	5	10
Trial 3	101.25	78.25	5	9
Mean	101.25	78.58	4	8.33
w/	Thickness	L135	L180	L225
Trial 1	110.25	83.25	6	11
Trial 2	110.25	83.25	6	11
Trial 3	110.25	83.25	7	12
Mean	110.25	83.25	6.00	11

Vector

w/o	Thickness (mm)	L135 (mm)	L180 (mm)	L225 (mm)
Trial 1	114.25	56.25	4	10
Trial 2	113.25	58.25	5	9
Trial 3	114.25	60.25	4	8
Mean	113.92	57.92	4.33	9.00
w/	Thickness	L135	L180	L225
Trial 1	128.25	64.25	6	13
Trial 2	129.25	67.25	6	9
Trial 3	128.25	70.25	5	8
Mean	128.58	67.58	5.67	10

A.2 Interface Pressure Measurement

J3

w/o	Max. pr. RBZ (mm Hg)	Max. pr. LBZ (mm Hg)	Total force (Newton)	RBZ force (Newton)	LBZ force (Newton)	CZ force (Newton)	RBZ Percent Force (%)	LBZ Percent Force (%)	CZ Percent Force (%)	Dispersion index (%)	No. of cells>5 mm Hg	Contact Area (mm ²)	PPI:RBZ (mm Hg)	PPI:LBZ (mm Hg)
1	76	42	394.48	45.43	32.45	0.84	11.52	8.23	0.21	19.96	118	86025.63	62	43
2	60	44	382.19	42.08	32.18	0.37	11.01	8.42	0.10	19.53	120	87483.70	53	43
3	70	52	380.88	49.77	41.36	2.55	13.07	10.86	0.67	24.60	127	92586.91	61	47
4	58	48	383.58	50.44	41.95	5.50	13.15	10.94	1.43	25.52	128	93315.94	56	44
5	60	55	384.49	52.44	43.46	5.49	13.64	11.30	1.43	26.37	130	94774.00	53	43
Mean	65	48	385.12	48.03	38.28	2.95	12.48	9.95	0.77	23.19	124.6	90837.24	57	44
w/	Max. pr. RBZ (mm Hg)	Max. pr. LBZ (mm Hg)	Total force (Newton)	RBZ force (Newton)	LBZ force (Newton)	CZ force (Newton)	RBZ Percent Force (%)	LBZ Percent Force (%)	CZ Percent Force (%)	Dispersion index (%)	No. of cells>5 mm Hg	Contact Area (mm ²)	PPI:RBZ (mm Hg)	PPI:LBZ (mm Hg)
1	48	46	369.03	31.56	31.17	0.30	8.55	8.45	0.08	17.08	125	91128.85	39	36
2	57	46	380.50	36.89	31.76	0.40	9.69	8.35	0.11	18.15	126	91857.88	43	39
3	52	47	378.65	36.35	32.52	0.93	9.60	8.59	0.25	18.44	123	89670.79	39	37
4	52	47	385.27	40.20	29.80	0.38	10.43	7.73	0.10	18.26	128	93315.94	45	41
5	53	50	378.12	40.13	30.43	0.66	10.61	8.05	0.18	18.84	128	93315.94	43	40
Mean	52	47	378.31	37.03	31.14	0.54	9.78	8.23	0.14	18.15	126	91857.88	42	39

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w/	Max. pr. RBZ (mm Hg)	Max. pr. LBZ (mm Hg)	Total force (Newton)	RBZ force (Newton)	LBZ force (Newton)	CZ force (Newton)	RBZ Percent Force (%)	LBZ Percent Force (%)	CZ Percent Force (%)	Dispersion index (%)	No. of cells>5 mm Hg	Contact Area (mm ²)	PPI:RBZ (mm Hg)	PPI:LBZ (mm Hg)
1	75	73	439.10	60.98	49.51	45.51	13.89	11.27	10.37	35.53	173	126122.3	62	50
2	90	79	457.47	72.70	54.32	43.95	15.89	11.87	9.61	37.38	168	122477.2	60	55
3	89	76	445.44	68.90	48.97	43.97	15.47	10.99	9.87	36.33	172	125393.3	59	52
4	83	75	453.75	67.19	52.96	49.71	14.81	11.67	10.96	37.43	167	121748.1	57	58
5	88	84	456.82	68.12	59.73	44.42	14.91	13.07	9.72	37.71	172	125393.3	71	61
Mean	85	77	450.51	67.58	53.10	45.51	14.99	11.78	10.10	36.88	170.4	124226.8	62	55

w/o	Max. pr. RBZ (mm Hg)	Max. pr. LBZ (mm Hg)	Total force (Newton)	RBZ force (Newton)	LBZ force (Newton)	CZ force (Newton)	RBZ Percent Force (%)	LBZ Percent Force (%)	CZ Percent Force (%)	Dispersion index (%)	No. of cells>5 mm Hg	Contact Area (mm ²)	PPI:RBZ (mm Hg)	PPI:LBZ (mm Hg)
1	57	68	375.96	50.72	44.79	39.33	13.49	11.91	10.46	35.87	163	118832	46	47
2	54	55	380.26	55.92	44.34	31.16	14.71	11.66	8.19	34.56	163	118832	50	47
3	52	56	372.73	53.63	46.25	28.33	14.39	12.41	7.60	34.40	167	121748.1	50	49
4	55	44	368.24	63.14	39.83	15.55	17.15	10.82	4.22	32.19	172	125393.3	54	41
5	52	59	383.95	47.30	47.23	24.79	12.32	12.30	6.46	31.08	173	126122.3	44	49
Mean	54	57	376.23	54.14	44.49	27.83	14.41	11.82	7.39	33.62	167.6	122185.6	49	47

Vector

w/o	Max. pr. RBZ (mm Hg)	Max. pr. LBZ (mm Hg)	Total force (Newton)	RBZ force (Newton)	LBZ force (Newton)	CZ force (Newton)	RBZ Percent Force (%)	LBZ Percent Force (%)	CZ Percent Force (%)	Dispersion index (%)	No. of cells>5 mm Hg	Contact Area (mm ²)	PPI:RBZ (mm Hg)	PPI:LBZ (mm Hg)
1	102	161	357.88	80.21	98.76	17.29	22.41	27.60	4.83	54.84	105	76548.23	80	101
2	122	147	363.88	78.76	96.16	24.95	21.65	26.43	6.86	54.93	108	78735.33	81	100
3	105	150	356.18	77.42	95.44	18.71	21.74	26.79	5.25	53.78	105	76548.23	74	101
4	120	113	359.22	82.14	85.57	24.97	22.87	23.82	6.95	53.64	110	80193.39	79	93
5	127	131	358.13	81.99	85.61	27.13	22.89	23.9	7.57	54.38	112	81651.45	80	99
Mean	115	140	359.06	80.11	92.31	22.61	22.31	25.71	6.29	54.31	108	78735.33	79	99
w/	Max. pr. RBZ (mm Hg)	Max. pr. LBZ (mm Hg)	Total force (Newton)	RBZ force (Newton)	LBZ force (Newton)	CZ force (Newton)	RBZ Percent Force (%)	LBZ Percent Force (%)	CZ Percent Force (%)	Dispersion index (%)	No. of cells>5 mm Hg	Contact Area (mm ²)	PPI:RBZ (mm Hg)	PPI:LBZ (mm Hg)
1	100	115	365.59	89.27	88.14	21.06	24.42	24.11	5.76	54.29	116	84567.57	82	97
2	108	106	350.37	81.40	83.74	37.53	23.23	23.90	10.71	57.84	119	86754.67	82	88
3	104	108	355.33	79.84	87.89	40.48	22.47	24.73	11.39	58.59	121	88212.73	82	88
4	79	107	355.36	70.63	84.16	58.90	19.88	23.68	16.57	60.13	121	88212.73	69	85
5	75	109	367.91	76.41	87.79	56.11	20.77	23.86	15.25	59.88	122	88941.76	69	87
Mean	93	109	358.91	79.51	86.35	42.81	22.15	24.06	11.94	58.15	119.8	87337.89	77	89

A.3 Horizontal Stiffness

J3

w/o	Peak Horizontal Force (N)	Final Horizontal Force (N)
1	111.94	82.76
2	134.53	107.61
3	137.44	109.17
Mean	127.97	99.85
w/	Peak Horizontal Force (N)	Final Horizontal Force (N)
1	99.56	69.79
2	53.77	32.95
3	91.89	66.16
Mean	81.74	56.30

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w/o	Peak Horizontal Force (N)	Final Horizontal Force (N)
1	68.26	52.87
2	68.73	57.43
3	75.70	62.96
Mean	70.89	57.75
w/	Peak Horizontal Force (N)	Final Horizontal Force (N)
1	61.46	47.96
2	67.51	53.60
3	63.03	48.51
Mean	64.00	50.03

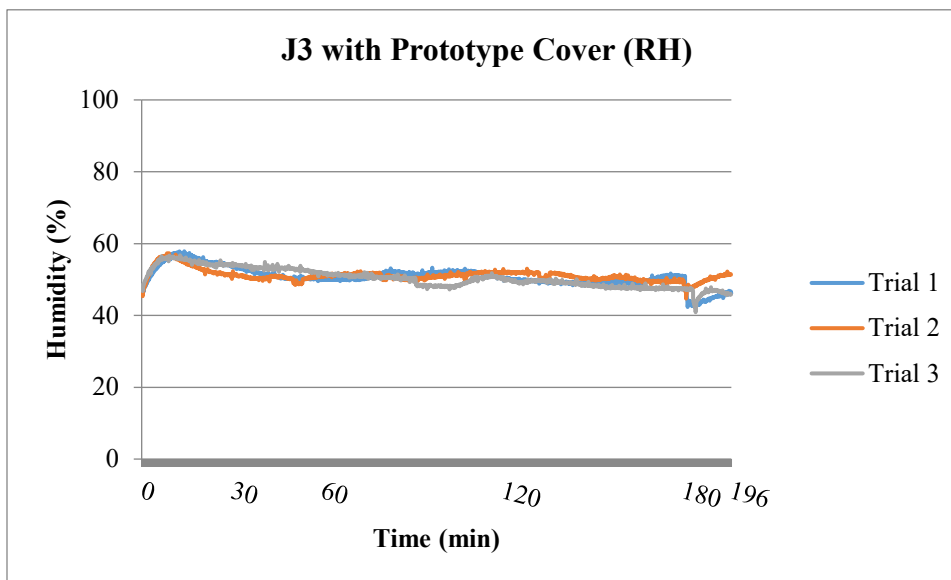
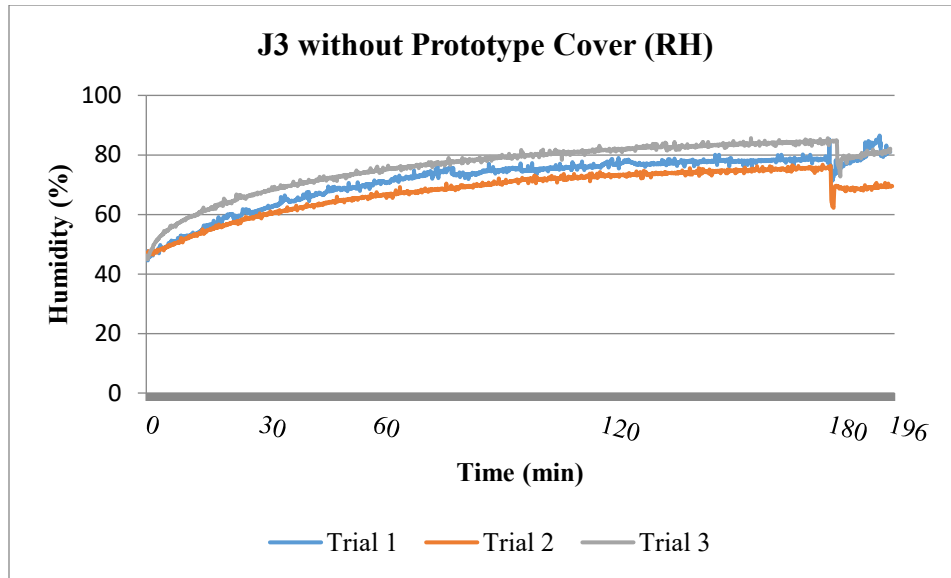
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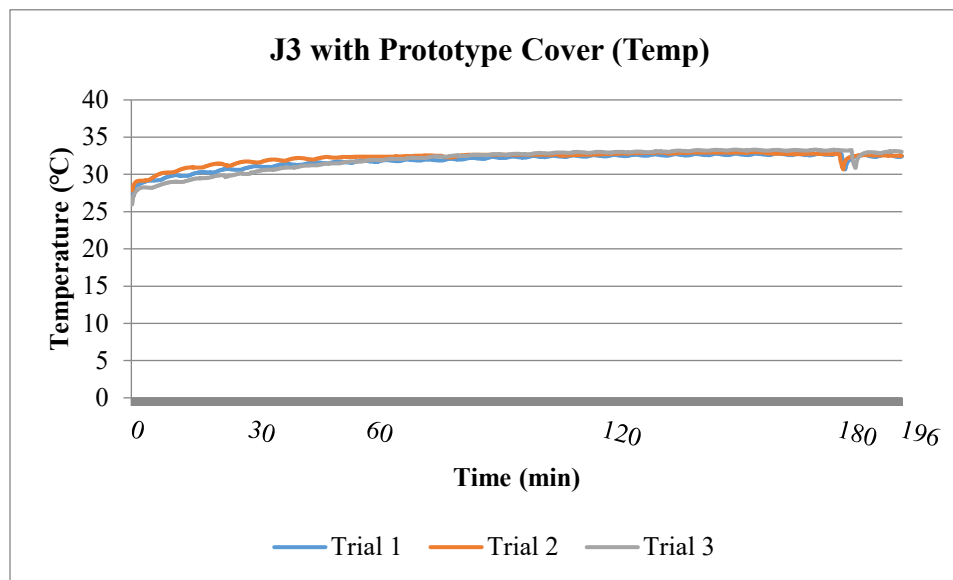
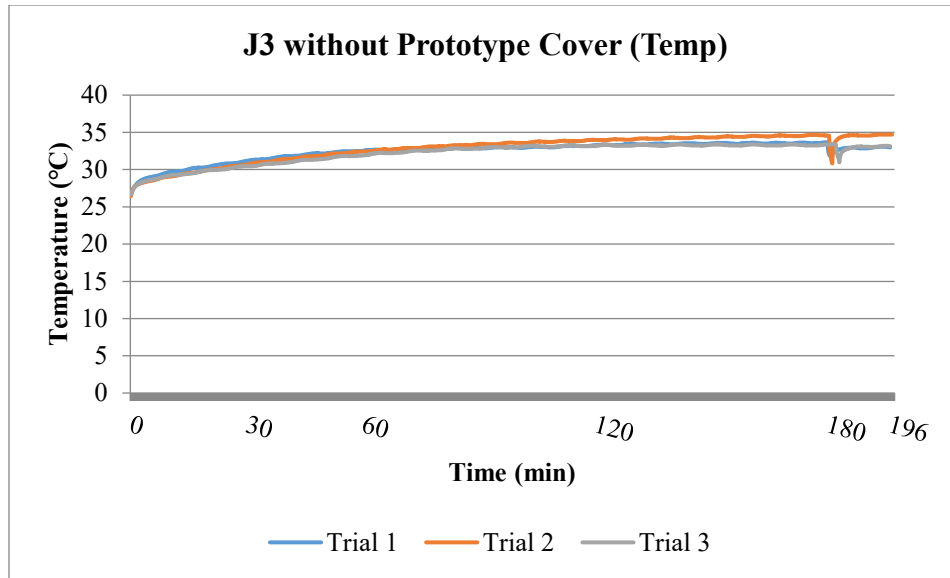
w/o	Peak Horizontal Force (N)	Final Horizontal Force (N)
1	164.19	128.45
2	143.50	105.68
3	129.72	92.73
Mean	145.81	108.95
w/	Peak Horizontal Force (N)	Final Horizontal Force (N)
1	92.80	64.51
2	106.70	76.48
3	105.46	77.23
Mean	101.65	72.74

A.4 Cushion Heat and Water Vapor Test

J3

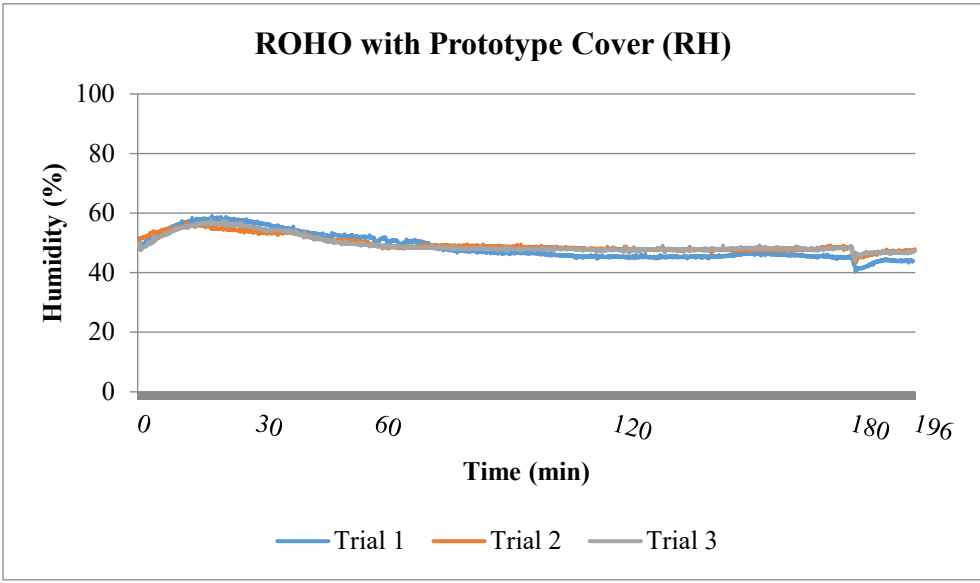
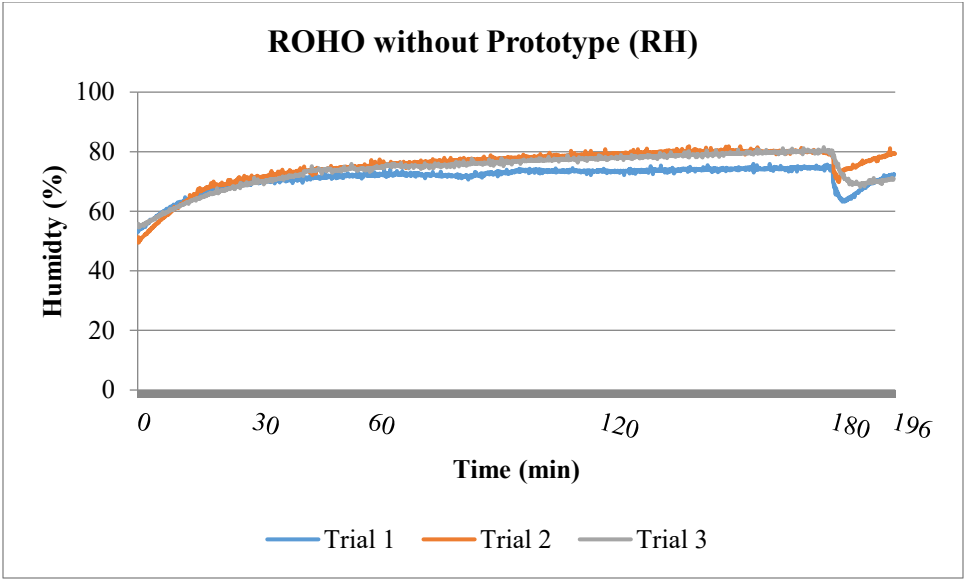
w/o	T0(%)	T60(%)	T120(%)	T180(%)	T181(%)	T196(%)	T0(°C)	T60(°C)	T120(°C)	T180(°C)	T181(°C)	T196(°C)
1	45.41	70.65	76.44	78.62	72.97	80.00	26.83	32.51	33.28	33.67	31.91	33.08
2	46.39	66.08	72.86	75.59	62.59	69.21	26.43	32.42	33.98	34.58	31.15	34.71
3	46.18	74.41	81.58	83.24	74.07	80.45	26.87	31.91	33.16	33.37	31.31	33.19
Mean	46.28	70.25	77.22	79.41	68.33	74.83	26.65	32.16	33.57	33.98	31.23	33.95
w/	T0(%)	T60(%)	T120(%)	T180(%)	T181(%)	T196(%)	T0(°C)	T60(°C)	T120(°C)	T180(°C)	T181(°C)	T196(°C)
1	47.06	50.00	50.40	50.85	44.33	45.95	27.51	31.80	32.44	32.79	31.04	32.36
2	46.69	50.93	52.00	50.07	46.59	52.64	28.06	32.37	32.70	32.72	30.77	32.52
3	48.17	51.98	50.24	47.46	42.18	46.23	26.04	31.87	33.00	33.28	30.87	33.12
Mean	47.30	50.97	50.88	49.46	44.37	48.27	27.20	32.01	32.71	32.93	30.89	32.67

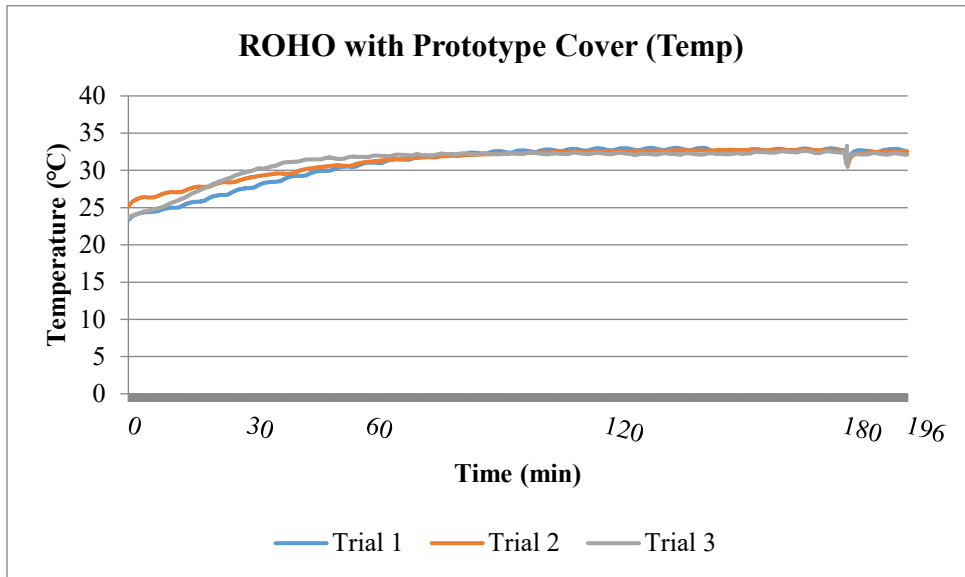
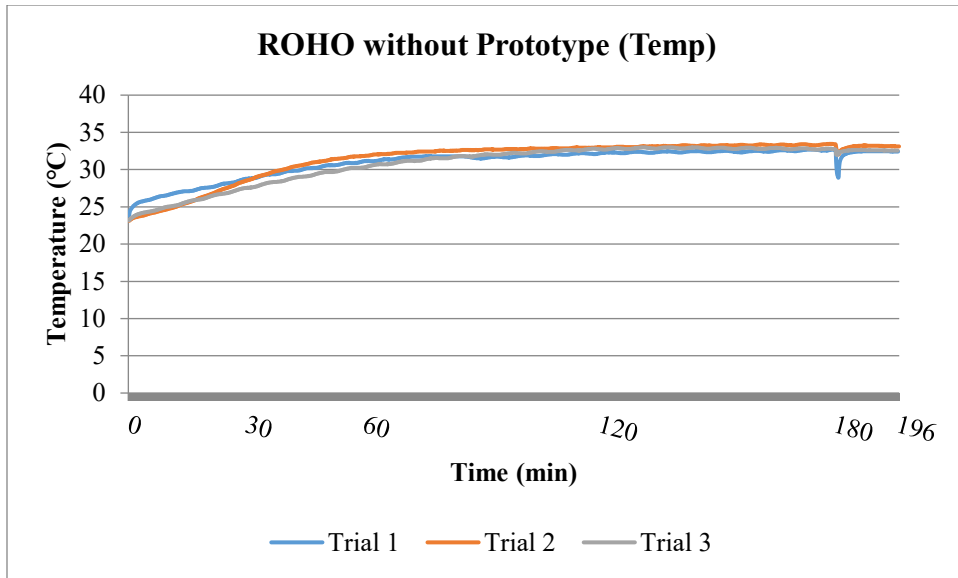




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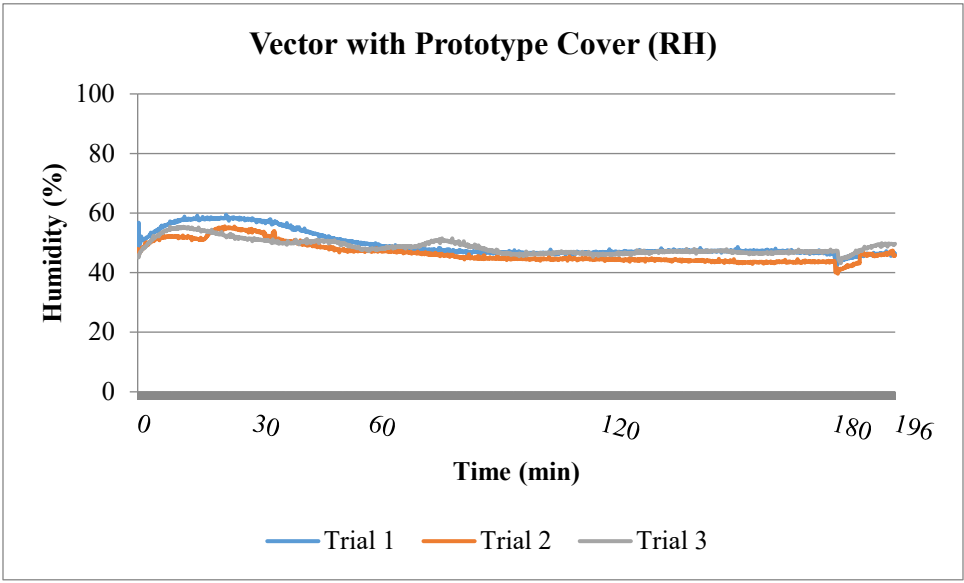
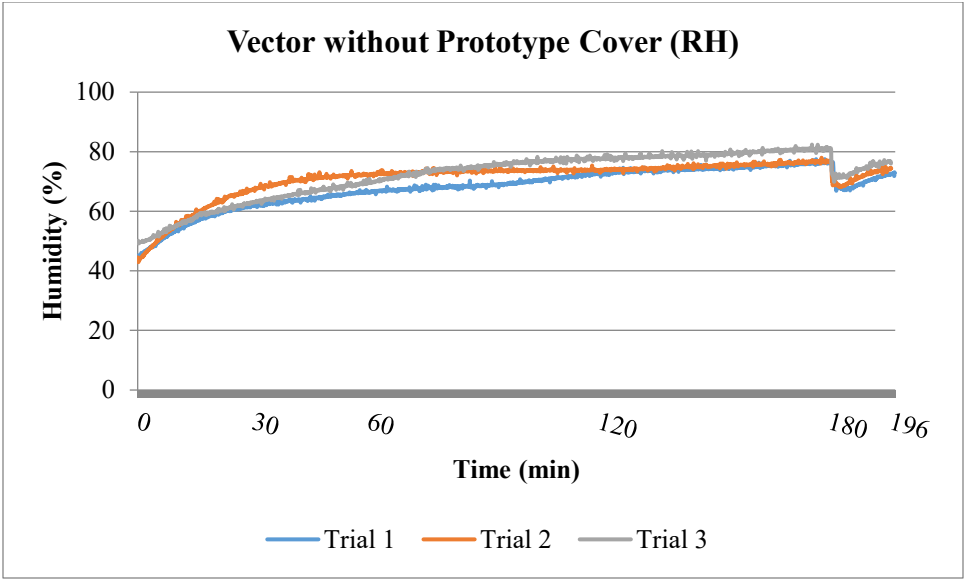
w/o	T0(%)	T60(%)	T120(%)	T180(%)	T181(%)	T196(%)	T0(°C)	T60(°C)	T120(°C)	T180(°C)	T181(°C)	T196(°C)
1	53.04	72.03	73.42	74.79	63.97	72.18	23.82	31.13	32.39	32.69	32.07	32.44
2	49.64	75.26	79.21	78.93	73.11	79.19	23.12	31.83	33.18	33.42	32.32	33.13
3	55.12	73.90	77.85	80.28	72.50	70.82	23.18	30.29	33.52	32.73	32.43	32.56
Mean	52.60	73.73	76.83	78.00	69.86	74.06	23.37	31.08	33.03	32.95	32.27	32.71
w/	T0(%)	T60(%)	T120(%)	T180(%)	T181(%)	T196(%)	T0(°C)	T60(°C)	T120(°C)	T180(°C)	T181(°C)	T196(°C)
1	51.52	50.80	45.49	45.24	41.85	43.98	23.42	31.03	32.74	32.70	31.12	32.69
2	50.46	49.09	47.81	48.51	46.67	47.47	25.26	31.13	32.60	32.66	30.76	32.56
3	49.84	48.99	47.54	49.04	44.88	46.73	23.74	31.79	32.33	32.46	33.30	32.16
Mean	50.60	49.63	46.95	47.60	44.47	46.06	24.14	31.32	32.56	32.61	31.73	32.47

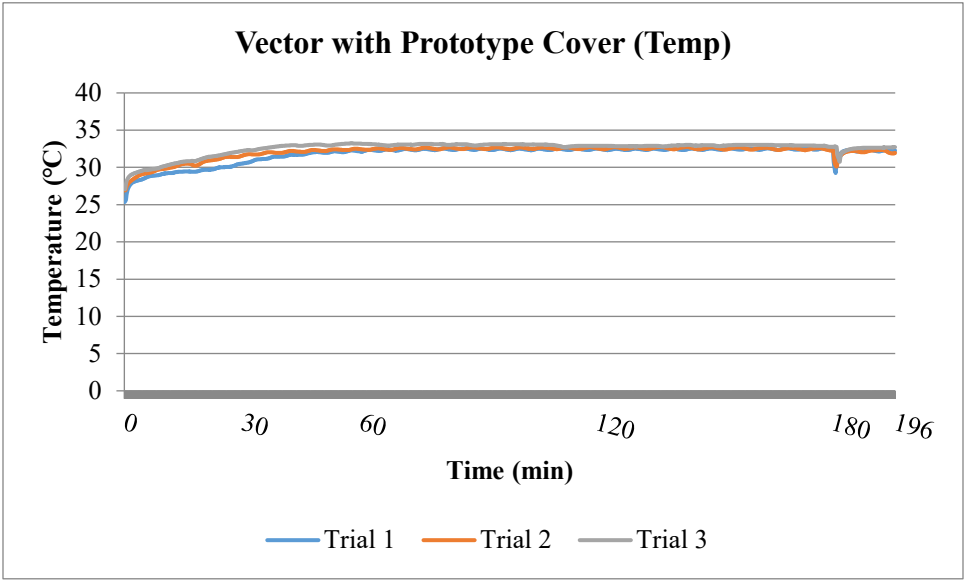
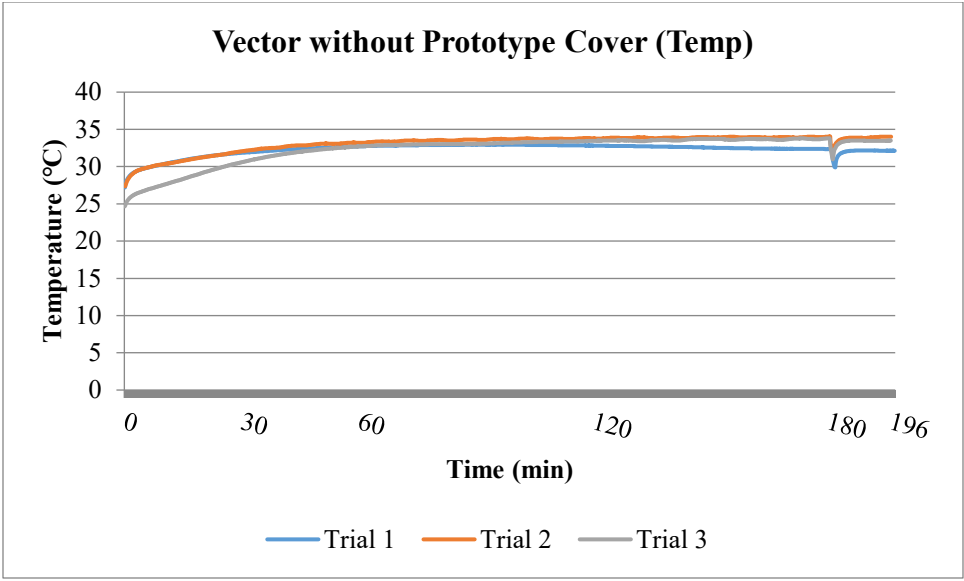




Vector

w/o	T0(%)	T60(%)	T120(%)	T180(%)	T181(%)	T196(%)	T0(°C)	T60(°C)	T120(°C)	T180(°C)	T181(°C)	T196(°C)
1	44.93	66.60	72.58	76.60	69.80	72.25	27.33	32.72	32.44	32.35	30.71	32.14
2	44.61	72.25	73.75	76.99	69.49	74.04	27.44	33.20	33.88	34.02	32.25	34.01
3	50.21	69.46	77.71	81.26	70.97	76.42	24.65	32.71	33.46	33.79	31.24	33.47
Mean	46.58	69.44	74.68	78.29	70.08	74.24	26.47	32.88	33.26	33.39	31.40	33.21
w/	T0(%)	T60(%)	T120(%)	T180(%)	T181(%)	T196(%)	T0(°C)	T60(°C)	T120(°C)	T180(°C)	T181(°C)	T196(°C)
1	48.55	49.63	46.87	46.50	42.93	45.62	25.35	32.13	32.52	32.44	29.25	32.38
2	48.02	47.49	44.49	43.96	41.02	46.86	27.02	32.45	32.60	32.27	30.10	31.90
3	45.77	47.81	46.28	47.15	43.56	49.65	27.10	33.19	32.89	32.78	30.79	32.69
Mean	47.45	48.31	45.88	45.87	42.51	47.38	26.49	32.59	32.67	32.50	30.05	32.32





Appendix B

B.1 Clinician Survey and Results

The wheelchair cushion cover with microclimate management:

FOCUS GROUP QUESTIONNAIRE

Subject ID: 01

Date: 4 / 11 / 19

What is your professional background?

Occupational therapist and assistive technology professional

How many years of experience as a rehabilitation professional do you have?

 30

Please share your feedback.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The cover with microclimate management is a suitable size.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The microclimate management system is simple to work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has the compatibility with current wheelchair cushions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management provides the comfort to the seated body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management helps reduce the moisture in the wheelchair seat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The microclimate management system works quietly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management can be easily washed and cleaned.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has a good overall appearance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Neutral because I did not know how laundering would impact the integrity of the cushion. Most covers can be washed very easily without causing too much wear on the material but for your cover I'm not sure.

If the cover with microclimate management was available for purchase, would you recommend it (clinicians) or use it (other wheelchair users)?

Yes

No

What price would be reasonable for this cover with microclimate management?

- 1) \$10~\$50
- 2) \$50~\$100
- X3) \$100~\$150
- 4) \$150~\$200
- 5) More than \$200

What kinds of benefits would people get from the cover with microclimate management?

Please explain your answer.

_____ decreased heat and possibly moisture.

What do you like most about the cover? Please explain your answer.

___It is pretty thin and doesn't add much bulk to the cushion. The motor seems pretty quiet. Looks like it will fit over most common commercial cushions. ___

What do you like least about the cover? Please explain your answer.

___Might increase the width of the cushion a little. Thigh guides might get in the way of pushing air out. One more thing that might be difficult for someone to maintain if they're not very compliant. ___

Please comment any improvement if you would like to redesign the cover with microclimate management.

___Perhaps thinner but not sure that's possible. _____

The wheelchair cushion cover with microclimate management:
FOCUS GROUP QUESTIONNAIRE

Subject ID: 002

Date: 19 / Apr / 2019

What is your professional background?

Occupational Therapist.

How many years of experience as a rehabilitation professional do you have?

10

Please share your feedback.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The cover with microclimate management is a suitable size.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The microclimate management system is simple to work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has the compatibility with current wheelchair cushions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management provides the comfort to the seated body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management helps reduce the moisture in the wheelchair seat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The microclimate management system works quietly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management can be easily washed and cleaned.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has a good overall appearance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Cover sizes are varied, will be good to have different sizes of custom cover

can be better if the zip is on the outside.

If the cover with microclimate management was available for purchase, would you recommend it (clinicians) or use it (other wheelchair users)?

Yes

No

What price would be reasonable for this cover with microclimate management?

- 1) \$10-\$50
- 2) \$50-\$100
- 3) \$100-\$150
- 4) \$150-\$200
- 5) More than \$200

because the cushion is very expensive.

What kinds of benefits would people get from the cover with microclimate management? Please explain your answer.

it works like a fan under the buttock. it helps with ventilation.

What do you like most about the cover? Please explain your answer.

it is lightweight. & it helps to reduce moisture.

What do you like least about the cover? Please explain your answer.

it has to be plugged on the have the microclimate management.

Please comment any improvement if you would like to redesign the cover with microclimate management.

simplify the cover - too many layers ^^

The wheelchair cushion cover with microclimate management:
FOCUS GROUP QUESTIONNAIRE

Subject ID: 03

Date: 4 / 26 / 19

What is your professional background?

OT

How many years of experience as a rehabilitation professional do you have?

1.5

Please share your feedback.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The cover with microclimate management is a suitable size.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The microclimate management system is simple to work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has the compatibility with current wheelchair cushions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management provides the comfort to the seated body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management helps reduce the moisture in the wheelchair seat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The microclimate management system works quietly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management can be easily washed and cleaned.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has a good overall appearance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

plastic piece may interfere w/ legs for some clients

no machine wash; wipe only

If the cover with microclimate management was available for purchase, would you recommend it (clinicians) or use it (other wheelchair users)?

Yes

No

What price would be reasonable for this cover with microclimate management?

- 1) \$10-\$50
- 2) \$50-\$100
- 3) \$100-\$150
- 4) \$150-\$200
- 5) More than \$200

What kinds of benefits would people get from the cover with microclimate management?
Please explain your answer.

reduce moisture that could lead to pressure injuries

What do you like most about the cover? Please explain your answer.

quietness

What do you like least about the cover? Please explain your answer.

must be plugged into outlet, limits mobility

Please comment any improvement if you would like to redesign the cover with microclimate management.

Battery pack!

The wheelchair cushion cover with microclimate management:

FOCUS GROUP QUESTIONNAIRE

Subject ID: 04

Date: 5 / 21 / 19

What is your professional background? Physical Therapist

How many years of experience as a rehabilitation professional do you have? 21

Please share your feedback.

Need to clinically trial

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The cover with microclimate management is a suitable size.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The microclimate management system is simple to work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has the compatibility with current wheelchair cushions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management provides the comfort to the seated body.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management helps reduce the moisture in the wheelchair seat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The microclimate management system works quietly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management can be easily washed and cleaned.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has a good overall appearance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If the cover with microclimate management was available for purchase, would you recommend it (clinicians) or use it (other wheelchair users)?

Yes

No

What price would be reasonable for this cover with microclimate management?

- 1) \$10~\$50
- 2) \$50~\$100
- 3) \$100~\$150
- 4) \$150~\$200
- 5) More than \$200

What kinds of benefits would people get from the cover with microclimate management?
Please explain your answer.

↓ tissue temperature

What do you like most about the cover? Please explain your answer.

concept, potential
for moisture prevention / improvement

What do you like least about the cover? Please explain your answer.

Utility with incontinent geriatric clients? how helpful?

Please comment any improvement if you would like to redesign the cover with microclimate management.

USB port ability to charge

The wheelchair cushion cover with microclimate management:

FOCUS GROUP QUESTIONNAIRE

Subject ID: 05

Date: 5 / 21 / 19

What is your professional background?

MPT, ATP

How many years of experience as a rehabilitation professional do you have?

25

Please share your feedback.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The cover with microclimate management is a suitable size.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The microclimate management system is simple to work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management has the compatibility with current wheelchair cushions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management provides the comfort to the seated body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management helps reduce the moisture in the wheelchair seat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The microclimate management system works quietly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The cover with microclimate management can be easily washed and cleaned.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The cover with microclimate management has a good overall appearance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

THOROUGH CLEANING AND DISINFECTING APPEARS TO BE LIMITED 2° ELECTRONICS. REMOVABLE ELECTRONICS WOULD HELP.

If the cover with microclimate management was available for purchase, would you recommend it (clinicians) or use it (other wheelchair users)?

Yes

No

What price would be reasonable for this cover with microclimate management?

1) \$10-\$50

2) \$50-\$100

3) \$100-\$150

4) \$150-\$200

5) More than \$200

What kinds of benefits would people get from the cover with microclimate management?

Please explain your answer.

DECREASED TEMP AND MOISTURE @ SEAT INTERFACE.

What do you like most about the cover? Please explain your answer.

ADDRESSES TWO IMPORTANT ISSUES (HEAT & MOISTURE)

What do you like least about the cover? Please explain your answer.

ABILITY TO CLEAN AND DISINFECT.

Please comment any improvement if you would like to redesign the cover with microclimate management.

BACTERIO STATIC MATERIALS. POSSIBLY 2
VERSIONS - INCONTINENT AND CONTINENT.

Bibliography

- Adams, M. J., Briscoe, B. J., & Johnson, S. A. (2007). Friction and Lubrication of Human Skin. *Tribology Letters*, 26, 239–253.
- Akins, J., Karg, P., & Brienza, D. (2008). Measurement & Analysis of Wheelchair Seat Cushions Shear Characteristics. In *RESNA Annual Conference*.
- Akins, J., Karg, P., & Brienza, D. (2011). Interface Shear and Pressure Characteristics of Wheelchair Seat Cushions. *The Journal of Rehabilitation Research and Development*, 48(3), 225–234.
- Atlas, E., Yizhar, Z., Khamis, S., Slomka, N., Hayek, S., & Gefen, A. (2009). Utilization of the Foot Load Monitor for Evaluating Deep Plantar Tissue Stresses in Patients with Diabetes: Proof-of-concept Studies. *Gait Posture*, 29, 377–382.
- Bauer, K., Nazzal, M., Jones, O., & Qu, W. (2016). Pressure Ulcers in the United States' Inpatient Population From 2008 to 2012: Results of a Retrospective Nationwide Study. *Ostomy Wound Management*, 28(3), 70–77.
- Bennett, L., Kavner, D., & Lee, B. et al. (1984). Skin Stress and Blood Flow in Sitting Paraplegic Patients. *Arch Phys Med Rehabil*, 65(4), 186–190.
- Bhushan, B., Chen, S., & Ge, S. (2012). Friction and Durability of Virgin and Damaged Skin with and without Skin Cream Treatment Using Atomic Force Microscopy. *J. Nanotechnol.*, 3, 731–746.
- Blattner, C. M., Coman, G., Blickenstaff, N. R., & Maibach, H. I. (2014). Percutaneous Absorption of Water in Skin: a review. *Rev. Environ. Health*, 29, 175–180.
- Brem, H., Maggi, J., & Nierman, D. (2010). High Cost of Stage IV Pressure Ulcers. *Am J Surg*, 200(4), 473–477.
- Brienza, D., & Geyer, M. J. (2000). *Support Surface Technology* (Vol. 10). Retrieved from <http://www.wheelchairnet.org/>
- Brienza, D., Kelsey, S., Karg, P., Allegretti, A., Olson, M., Schmeler, M., ... Holm, M. (2010). A Randomized Clinical Trial on Preventing Pressure Ulcers with Wheelchair Seat Cushions. *Journal of the American Geriatrics Society*, 58(12), 2308–2314. <https://doi.org/10.1111/j.1532-5415.2010.03168.x>
- Burton, A., & Yamada, S. (1951). Relation between Blood Pressure and Flow in the Human Forearm. *J Appl Physiol*, 4(5), 329–339.

- Coleman, S., Gorecki, C., Nelson, E. ., Closs, S. J., Defloor, T., Halfens, R., ... Nixon, J. (2013). Patient Risk Factors for Pressure Ulcer Development: Systematic Review. *Int. J. Nurs. Stud.*, *50*, 974–1003.
- Cravello, B., & Ferri, A. (2008). Relationships between Skin Properties and Environmental Parameters. *Skin Res. Technol*, *14*, 180–186.
- Dealey, C., Brindle, C. T., Black, J., Alves, P., Santamaria, N., Call, E., & Clark, M. (2015). Challenges in Pressure Ulcer Prevention. *International Wound Journal*, *12*(3), 309–312. <https://doi.org/10.1111/iwj.12107>
- Denne, W. B. (1981). The “Hammock” Effect in Wheelchair Cushion Covers. *International Medical Society of Paraplegia*, *19*, 38–42.
- Dobos, G., Gefen, A., Blume-Peytavi, U., & Kottner, J. (2015). Weight-bearing-induced Changes in the Microtopography and Structural Stiffness of Human Skin in Vivo Following Immobility Periods. *Wound Repair Regen*, *23*, 37–43
- Edsberg, L. (2007). Pressure Ulcer Tissue Histology: An Appraisal of Current Knowledge. *Ostomy Wound Manage*, *53*(10), 40 – 49.
- Egawa, M., Oguri, M., Kuwahara, T., & Takahashi, M. (2002). Effect of Exposure of Human Skin to a Dry Environment. *Skin Res. Technol.*, *8*, 212–218.
- Elias, P. (1981). Epidermal Lipids, Barrier Function, and Desquamation. *J Invest Dermatol*, *80*, 44–49.
- Engelbrechtsen, K. A., Johansen, J.D., Kezic, S., Linneberg, A., & Thyssen, J. P. (2016). The Effect of Environmental Humidity and Temperature on Skin Barrier Function and Dermatitis. *J. Eur. Acad. Dermatol. Venereol*, *30*, 223–249.
- Faergemann, J., Aly, R., Wilson, D. R., & Maibach, H. I. (1983). Skin Occlusion: Effect on Pityrosporum Orbiculare, Skin PCO₂, pH, Transepidermal Water Loss, and Water Content. *Arch. Dermatol. Res.*, *275*, 383–387. <https://doi.org/doi/10.1007/BF00417338>
- Ferguson-Pell, M., Hirose, H., Nicholson, G., & Call, E. (2010). Thermodynamic Rigid Cushion Loading Indenter: A Buttock-shaped Temperature and Humidity Measurement System for Cushioning Surfaces under Anatomical Compression Conditions. *The Journal of Rehabilitation Research and Development*, *46*(7), 945. <https://doi.org/10.1682/jrrd.2008.10.0142>
- Fisher, S., Szymke, T., Apte, S., & Kosiak, M. (1978). Wheelchair Cushion Effect on Skin Temperature. *Arch Phys Med Rehabil*, *59*, 68–72.
- Fluhr, J. W., Darlenski, R., Angelova-Fischer, I. Tsankov, N., & Basketter, D. (2008). Skin Irritation and Sensitization: Mechanisms and New Approaches for Risk Assessment. 1. Skin Irritation. *Skin Pharmacol. Physiol.*, *21*, 124–135.

- Gawlitta, D., Li, W., Oomens, C., Baaijens, F., Bader, D., & Bouten, C. (2007). The Relative Contributions of Compression and Hypoxia to Development of Muscle Damage: An in Vitro Study. *Annals of Biomedical Engineering*, 35(2), 273–284.
- Gefen, A. (2011). How Do Microclimate Factors Affect the Risk for Superficial Pressure Ulcers: A Mathematical Modeling Study. *J. Tissue Viability*, 20, 81–88.
- Gefen, A., Nierop, B., Bader, D., & Oomens, C. (2008). Strain-time Cell-death Threshold for Skeletal Muscle in a Tissue-engineered Model System for Deep Tissue Injury. *Journal of Biomechanics*, 41, 2003–2012.
- Gerhardt, L. C., Strassle, V., Lenz, A., Spencer, N. D., & Derler, S. (2008). Influence of Epidermal Hydration on the Friction of Human Skin against Textiles. *J. R. Soc*, 5, 1317–1328.
- Goldberg, M. (2012). General Acute Care. In B. Pieper (Ed.), *Pressure Ulcers: Prevalence, Incidence, and Implications for the Future*. (pp. 27–46). Washington, DC: NPUAP.
- Hsu, T. W., Yang, S. Y., Liu, J. T., Pan, C. T., & Yang, Y. S. (2018). The Effect of Cushion Properties on Skin Temperature and Humidity at the Body-support Interface. *Assistive Technology*, 30(1), 1–8. <https://doi.org/10.1080/10400435.2016.1223208>
- Husain, T. (1953). An Experimental Study of Some Pressure Effects on Tissues, with Reference to the Bedsore Problem. *J Pathol Bacteriol*, 66(2), 347 – 358.
- Iaizzo, P. A., Kveen, G. L., Kokate, J. Y., Leland, K. J., Hansen, G. L., & Sparrow, E. M. (1995). Prevention of Pressure Ulcers by Focal Cooling - Histological Assessment in a Porcine Model. *Wounds—a Compendium of Clinical Research and Practice*, 7, 161–169.
- Igaki, M., Higashi, T., Hamamoto, S., Kodama, S., Naito, S., & Tokuhara, S. (2014). A Study of the Behavior and Mechanism of Thermal Conduction in the Skin under Moist and Dry Heat Conditions. *Skin Res. Technol*, 20, 43–49.
- Imhof, R. E., De Jesus, M. E., Xiao, P., Ciorrea, L. I., & Berg, E. P. (2009). Closed-chamber Transepidermal Water Loss Measurement: Microclimate, Calibration and Performance. *Int. J. Cosmet. Sci.*, 31(97–118).
- International Organization for Standardization. (2015). Wheelchair Seating - Part 6: Simulated Use and Determination of the Changes in Properties of Seat Cushions. ISO16840-6:2015, Geneva, Switzerland.
- International Organization for Standardization. (2018a). Wheelchair Seating - Part 2: Determination of Physical and Mechanical Characteristics of Seat Cushions Intended to Manage Tissue Integrity. ISO 16840-2:2018(E), Geneva, Switzerland.
- International Organization for Standardization. (2018b). Wheelchair Seating - Part 7: Cushion Heat & Water Vapour Testing. ISO 16840-7:2018, Geneva, Switzerland.

- Jonathan, S. A. (2008). *Investigation OF Interface Shear Stresses on Wheelchair Seat*. University of Pittsburgh.
- Knapik, J. J., Reynolds, K. L., Duplantis, K. L., & Jones, B. H. (1995). Friction Blisters. Pathophysiology, Prevention and Treatment.]. *Sports Medicine*, 20(3), 136–147.
- Kokate, J. ., Leland, K. J., Held, A. M., Hansen, G. L., Kveen, G. L., Johnson, B. A., ... Laizzo, P. A. (1995). Temperature-modulated Pressure Ulcers: A Porcine Model. *Arch. Phys. Med. Rehabil.*, 76, 666–673.
- Kosiak, M. (1961). Etiology of Decubitus Ulcers. *Arch Phys Med Rehabil*, 42, 19–29.
- Kosiak, M., Kubicek, W., & Olson, M. et al. (1958). Evaluation of Pressure as a Factor in the Production of Ischial Ulcers. *Arch Phys Med Rehabil*, 39(10), 623 – 629.
- Kottner, J., & Beeckman, D. (2015). Incontinence-associated Dermatitis and Pressure Ulcers in Geriatric Patients. *G. Ital. Dermatol. Venereol*, 150, 717–729.
- Kottner, Jan, Black, J., Call, E., Gefen, A., & Santamaria, N. (2018). Microclimate: A Critical Review in the Context of Pressure Ulcer Prevention. *Clinical Biomechanics*, 59(March), 62–70. <https://doi.org/10.1016/j.clinbiomech.2018.09.010>
- Kovalev, A. E., Dening, K., Persson, B. N., & Gorb, S. N. (2014). Surface Topography and Contact Mechanics of Dry and Wet Human Skin. *J. Nanotechnol*, 5, 1341–1348.
- Krouskop, T. (1983). A Synthesis of the Factors that Contribute to Pressure Sore Formation. *Med Hypotheses*, 11(2), 255 – 267.
- Kumar, V., Fausto, N., & Abbas, A. (2005). Acute and Chronic Inflammation. In *Robbins and Cotran pathologic basis of disease* (7th ed.). Philadelphia.
- Lachenbruch, C. (2005). Skin Cooling Surfaces: Estimating the Importance of Limiting Skin Temperature. *Ostomy Wound Manage*, 51(2), 70–79.
- Leaf Healthcare. (2014). The Financial Impact of Pressure Ulcers, 1–4. Retrieved from http://www.leafhealthcare.com/pdfs/LH_WP_FinancialOverview_1563AA_PDF_100514.pdf
- Lindan, O. (1961). Etiology of Decubitus Ulcers: An Experimental Study. *Arch Phys Med Rehabil*, 42, 774 – 783.
- Local Coverage Article : Wheelchair Seating - Policy Article (A52505)*. (2019).
- Mayrovitz, H. Z., & Sims, N. (2001). Biophysical Effects of Water and Synthetic Urine on Skin. *Adv. Skin Wound Care*, 14, 302–308.
- McDonald, J. H. (2014). *Handbook of Biological Statistics* (3rd ed.). Baltimore, Maryland: Sparky House Publishing.

- Morita, T., Tujimura, K., Matsuda, K., & Yamada, T. (2012). The Hammock Effect of Wheelchair Cushion Covers: Persistent Redness over the Ischial Tuberosities in a Patient with Spinal Cord Injury - A Case Report. *Journal of Tissue Viability*, 21(4), 125–129. <https://doi.org/10.1016/j.jtv.2012.08.001>
- Nakgami, G., Sanada, H., Kitagawa, A., Tadaka, E., Maekawa, T., Nagase, T., & Konya, C. (2006). Incontinence Induces Stratum Corneum Vulnerability and Impairs the Skin Barrier Function in the Perianal Region. *Dermatology*, 213, 293–299.
- National Pressure Ulcer Advisory Panel Support Surface Standards Initiative Terms and Definitions Related to Support Surfaces*. (2018). Retrieved from https://www.npuap.org/wp-content/uploads/2012/03/NPUAP_S3I_TD.pdf
- Nilsson, G. (1977). Measurement of Water Exchange through Skin. *Med Biol Eng Comput*, 15, 209–218.
- NPUAP/EPUAP/PPPIA. (2014). Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. (pp. 1–308). Perth, Australia. Retrieved from <http://internationalguideline.com/>
- NPUAP, N. P. U. A. P. (2014). *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline*. (Vol. www.npuap.).
- Olesen, C., de Zee, M., & Rasmussen, J. (2010). Missing Links in Pressure Ulcer Research - An Interdisciplinary Overview. *J Appl Physiol*, 108(6), 1458 – 1464.
- Oomens, C., Bader, D., Loerakker, S., & Baaijens, F. (2015). Pressure Induced Deep Tissue Injury Explained. *Annals of Biomedical Engineering*, 42(2), 297–305.
- Padula, W. V., & Delarmente, B. A. (2019). The National Cost of Hospital-acquired Pressure Injuries in the United States. *International Wound Journal*, 1–7. <https://doi.org/10.1111/iwj.13071>
- Patel, S., Knapp, C. F., Donofrio, J. C., & Salcido, R. (1999). Temperature Effects on Surface Pressure-induced Changes in Rat Skin Perfusion: Implications in Pressure Ulcer Development. *JRRD*, 36(3), 189–201.
- Pedersen, L., & Jemec, G. B. (2006). Mechanical Properties and Barrier Function of Healthy Human Skin. *Acta Derm. Venereol.*, 86, 308–311.
- Persson, B. N. J., Kovalev, A., & Gorb, S. N. (2013). Contact Mechanics and Friction on Dry and Wet Human Skin. *Tribol. Lett.*, 50, 17–30.
- Petrofsky, J. S., Berk, L., Alshammari, F., Lee, H., Hamdan, A., Yim, J. E., ... Al-Nakhli, H. (2012). The Interrelationship between Air Temperature and Humidity as Applied Locally to the Skin: the Resultant Response on Skin Temperature and Blood Flow with Age Differences. *Med. Sci. Monit.*, 18(CR201–208).

- Pieper, B. (2012). Long term care/nursing homes. In B. Pieper (Ed.), *Pressure Ulcers: Prevalence, Incidence, and Implications for the Future*. (pp. 65–88). Washington, DC: NPUAP.
- Pieper, B. (2015). Pressure Ulcers: Impact, Etiology, and Classification. In *Acute and Chronic Wounds: Current Management Concepts* (pp. 124–139).
- Reddy, M., Gill, S., Kalkar, S., Wu, W., Anderson, P., & Rochon, P. (2008). Treatment of Pressure Ulcers: A Systematic Review. *JAMA*, *300*(22), 2647–2662.
- Reger, S., Adams, T., Madklebust, J., & Sahgal, V. (2001). Validation Test for Climate Control on Air-loss supports. *Arch Rhys Med Rehabil.*, *82*(5), 597–603.
- Russo, A., Steiner, C., & Spector, W. (2008). United States Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project Methods Series: Hospitalizations Related to Pressure Ulcers among Adults 18 years and Older. 2006, 1–9. Retrieved from www.hcup-us.ahrq.gov/toolsoftware/ccs/ccs.jsp
- Schwartz, D., Magen, Y. K., Levy, A., & Gefen, A. (2018). Effects of Humidity on Skin Friction against Medical Textiles as Related to Prevention of Pressure Injuries. *International Wound Journal*, *15*(6), 866–874. <https://doi.org/10.1111/iwj.12937>
- Skin IQ | Arjo. (2019). Retrieved May 21, 2019, from <https://www.arjo.com/int/products/pressure-injury-prevention---pip/skin-iq-family/skin-iq-629afd41/>
- Skin IQ Instruction for Use Microclimate Manger*. (2019).
- Sopher, R., & Gefen, A. (2011). Effects of Skin Wrinkles, Age and Wetness on Mechanical Loads in the Stratum Corneum as Related to Skin Lesions. *Med. Biol. Eng. Comput.*, *49*, 97–105.
- Sprigle, S., Dunlop, W., & Press, L. (2003). Reliability of Bench Tests of Interface Pressure. *Asst Technol*, *15*, 49–57.
- Sprigle, S., & Press, L. (2003). Reliability of the ISO Wheelchair Cushion Test for Loaded Contour Depth. *Asst Technol*, *15*, 145–150.
- Tagami, H., Kobayashi, H., Zhen, X. S., & Kikuchi, K. (2001). Environmental Effects on the Functions of the Stratum Corneum. *J. Investig. Dermatol. Symp. Proc*, *6*, 87–94.
- Ulrich, K. T., & Eppinger, S. D. (2000). Product, Design and Development. *Irwin McGraw-Hill*.
- Van Den Bos, J., Rustagi, K., & Gray, T. (2011). The \$17.1 Billion Problem: The Annual Cost of Measurable Medical Errors. *Health Aff (Millwood)*, *30*(4), 596–603.
- Van Gilder, C., Amlung, S., & Harrison, P. (2009). Results of the 2008-2009 International Pressure Ulcer Prevalence Survey and a 3-year, Acute care, Unit-specific analysis. *OSTOMY WOUND MANAGEMENT*, *55*(11), 39–45.

- Warner, R. R., Stone, K. J., & Boissy, Y. L. (2003). Hydration Disrupts Human Stratum Corneum Ultrastructure. *J. Invest. Dermatol.*, *120*, 275–284.
- Wilkes, G. L., Brown, I. A., & Wildnauer, R. H. (1973). The Biomechanical Properties of Skin. *CRC Crit. Rev. Bioeng*, *1*, 453–495.
- Worsley, P. R., & Bader, D. L. (2018). A Modified Evaluation of Spacer Fabric and Airflow Technologies for Controlling the Microclimate at the Loaded Support Interface. *Textile Research Journal*. <https://doi.org/10.1177/0040517518786279>
- Xiaohua, Y., Hong, H., & Xunwei, F. (2008). Development of the Warp Knitted Spacer Fabrics for Cushion Applications. *Journal of Industrial Textiles*, *37*(3), 213–223. <https://doi.org/10.1177/1528083707081592>
- Zhen, Y.-X., Suetake, T., & Tagami, H. (1999). Number of Cell Layers of the Stratum Corneum in Normal Skin - Relationship to the Anatomical Location on the Body, Age, Sex and Physical Parameters. *Arch Dermatol Res*, *291*, 555–559.