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A REVIEW OF FACTORS, SEATING DESIGN, AND SHAPE CAPTURE METHODS FOR
REDUCING PRESSURE INJURY RISK

A dissertation submitted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy in Health Related Sciences at Virginia Commonwealth University.

by

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Acknowledgments

I would like to share my deepest and sincerest appreciation for those who have supported me through this challenging and transformational journey.

To Dr. Tony Gentry, for your mentorship, optimism, efforts, and patience in reading countless drafts of this work, including the initial proposed dissertation which was ultimately upended by the 2020 pandemic.

To my parents, Manuel and Olivia for their never-ending support, faith, and prayers. Your work ethic and perseverance in all facets of your life have been an ongoing inspiration throughout mine.

To my 'in-laws', Bonnie and Rafael, who have inspired me to embrace the art, music, and spirit of life.

And last but not least, to my wife, Galilee, and children, Liana, and Sebastian. When I started this PhD program, I promised that I would not allow it to interfere with the routine and balance of our wonderful home life. I know now that was an impossibility, as I have spent many days, weekends, nights, and holidays locked up in our home office to see this process through. Your ongoing support, guidance, and love provided me the strength to carry-on when I needed it most. We have earned this together!

Vita

John Assis Damiao was born February 3, 1976, in Newark, New Jersey. He graduated from Queen of Peace High School, North Arlington, New Jersey in 1994. During these formative years, he worked in the family-owned auto repair business during non-school hours. He received his Applied Associates in Science in Occupational Therapy Assistant in 2000, followed by a Bachelor of Science/Master of Science in Occupational Therapy in 2009. He worked with individuals with developmental disabilities at the 1st Cerebral Palsy of NJ, Belleville, New Jersey (2000-2010) and The Center for Discovery, Harris, New York (2010-2017) specializing in assistive technologies. He moved to the academic setting in 2017, teaching and conducting research at Dominican College of Blauvelt, New York, followed by Pace University, New York in 2020.

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Abstract

A REVIEW OF FACTORS, SEATING DESIGN, AND SHAPE CAPTURE METHODS FOR REDUCING PRESSURE INJURY RISK

By John Damiao, MS, OTR/L (PhD Candidate)

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Health Related Sciences with a Concentration in Occupational Therapy at Virginia Commonwealth University.

Virginia Commonwealth University, 2020.

Major Director: Tony Gentry PhD, OTR/L, FAOTA
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This dissertation in the form of three papers ready for submission to peer-reviewed journals is submitted toward the requirements of the PhD in Health Related Sciences program at Virginia Commonwealth University. Chapter One provides an introductory overview of the project, including: (a) an overview of pressure injuries, (b) the impact of seating as an intervention, and (c) aims of the three-paper dissertation in addressing various aspects of pressure injury prevention. Each paper is unique and singular in its focus, yet all share the overlying aim of addressing pressure injury risk associated with wheelchair seating. Paper One describes the unique facilitators and barriers associated with pressure injury prevention practices among individuals with upper motor neuron lesions. Paper Two consists of a systematic review of the literature on the comparative effectiveness of various wheelchair seat cushions in reducing pressure injuries. Paper Three presents the results of a pilot study of a unique shape-capture method for custom-fitted wheelchair cushions conducted by the student researcher.

1. Introduction Chapter. A Review of Factors, Seating Design, and Shape Capture Methods for Reducing Pressure Injury Risk

1.1. Introduction

The purpose of this 3-paper dissertation is to address gaps in the literature regarding three interrelated topics: (1) the effectiveness of wheelchair seating on pressure injury prevention related to individuals with upper motor neuron lesions, (2) pressure relieving cushion design/materials, and (3) custom contoured shape capture methods. Specifically, *Paper One* focuses on the unique challenges of pressure injury management among individuals with severe mobility impairments related to upper motor neuron lesions. *Paper Two* focuses on the evidence of the effectiveness of wheelchair seat cushions to reduce pressure injuries across the various styles of seating design and materials. *Paper Three* analyzes retrospective data gathered from a pilot study comparing an innovation in custom-contoured seating design to off-the-shelf pressure relieving cushions.

1.2. Overview

Pressure injury (PI) is a contemporary term for what has previously been referred to as pressure ulcers, pressure sores or decubitus ulcers. A PI refers to damage that may occur on weight bearing skin underlying a bony prominence. The extent of damage can range from skin redness to full tissue deterioration, where the underlying structures, such as bone, are visible (Al Mutairi & Hendrie, 2018).

PIs are complex and rarely attributable to one single factor, instead being described as a systems failure (Jackson et al., 2010). PIs can result from mobility impairment and stationary positioning leading to continuous pressure of bony prominences on the skin. Extrinsic risk

factors, such as moisture, pressure, and frictional skin stressors, as well as intrinsic factors such as poor nutrition, low blood pressure, elevated body temperature, and smoking, can increase this risk (Bauer, 2012). This injury to the skin occurs most commonly as a result of pressure, friction, shear forces or any combination of these (Al Mutairi & Hendrie, 2018). When these biomechanical factors co-exist with declining health conditions or chronic illness, the risk for developing a PI increases dramatically (Bauer, 2012).

PIs are linked to 60,000 deaths every year in the United States, according to The Agency for Healthcare Research and Quality (2014). The Healthcare Cost Utilization Project reports 11.6% of patients die from PIs acquired in hospitals. Similarly, 4.5% of Medicare patients die from hospital acquired PIs (Padula et al., 2017). However, mortality is not the only devastating impact on patients. Living with PIs, especially severe cases, is often associated with pain, infection, amputation, emotional suffering, prolonged hospital stays, and significant costs (Cogan et al., 2017; Gunningberg, et al. 2018). In general, PIs place a significant burden on the healthcare system, while also impacting the quality of life of individuals and their caregivers (Badia et al., 2016). This impact can be associated with depression, helplessness, and anxiety, as PI prevention can be a life-long commitment for those with permanent mobility impairments (Augustin, 2013).

The costs associated with PIs is estimated at \$10B per year (Al Mutairi & Hendrie, 2018). This financial strain and impact on health continues to affect individuals, payers, and providers, despite continued efforts to address PI risk and prevention through education, identification, programming, and application of technology and equipment. The incidence and cost can be expected to increase as the population grows older and more vulnerable, and as

improvements in healthcare continue to extend the lives of individuals with severe medical conditions (Al Mutairi & Hendrie, 2018).

1.3. Seating as an Intervention

Individuals with severe motor impairments and upper motor neuron lesions (UMNLs), such as spinal cord injury, quadriplegia, cerebral vascular accident, cerebral palsy, traumatic brain injury and amyotrophic lateral sclerosis, often have significant ambulation impairments leading to dependence on wheeled mobility, putting them at risk for developing PIs (Freundlich et al., 2017), and requiring special or custom seating accommodations and interventions (Trefler, 1991). According to Trefler (1991), an evaluation of a seating system for this population should focus on determining which physical deformities can be corrected, and which must be accommodated. Seating solutions for this population may consist of planar, off-the-shelf contoured, or custom-contoured seating. These different seating systems serve different purposes, and thus a careful assessment must be conducted in order to assure optimal pressure relief, quality of life, and functional independence (Trefler, 1991).

Pressure management is an important aspect of care for individuals with UMNLs, but research literature in this area is extremely limited, as most PI management research is centered on people with spinal cord injuries (Freundlich et al., 2017). Extrapolating geriatric and/or spinal cord injury research to this population is not recommended. Freundlich et al. (2017) describes this population as needing a unique approach to PI management that addresses differences, such as body deformities, different head to body weight ratios (in children), and muscle tone imbalances.

1.4. Pressure Injury in Occupational Therapy Practice

This dissertation addresses the role of wheelchair seating on reduction of PI risk, a concern that is within the scope of occupational therapy (OT) practice. Addressing PIs is informed by the Occupational Therapy Practice Framework: Domain and Process, 3rd edition (OTPF 3rd). This document describes the scope of practice particularly as it pertains to promotion of occupation and function in activities of daily living. One of the domains that relates specifically to PI management is categorized as *Client Factors*, specifically *body functions* and *body structures*, which consists of physiological functions as well as anatomical structures. Yet another, domain is *occupations*, specifically *functional mobility* which consists of wheelchair usage, transfers, and moving from one position to another (American Occupational Therapy Association, 2014). Thus, it is appropriate for occupational therapists working with at-risk populations to address the management, prevention, and remediation of PIs, particularly as this effort pertains to mobility, function, participation, and independence.

OTs are a critical part of the interdisciplinary team responsible for PI management (Clarkson, et al 2019). The methods they use to address PIs can consist of assessing, recommending, and fitting of seating devices, as well as addressing positioning, weight shifting education, and collaboration with other professionals. Behavioral and educational programs are commonly applied to at-risk populations, as well as community support programming (Stinson, Gillan, & Porter-Armstrong, 2013).

A systematic review published by Kottner et al. (2018) found 146 quality indicators intended to improve prevention and management of PIs in the literature globally. The quality indicators that most directly address pressure ulcer prevention as related to occupational therapy practice are: (a) individualized care and intervention planning, (b) instruction and support for

repositioning and documentation, and (c) availability and application of pressure redistribution devices.

Similarly Macens, Rose, & Mackenzie (2011) describe the most frequently used PI interventions in OT practice as: (a) the application of pressure relieving seating surfaces and mattresses, (b) education of the client in weight shifting and skin care/inspection, repositioning, and transfer training, and (c) the promotion of functional activity with attention to pressure reduction. An exploratory study by Macens, et al. (2011) emphasizes the need for improved standards of care, procedures, and measures in addressing the risk of PIs, particularly among individuals with complex health needs.

The focus of OT intervention should be firmly rooted in a holistic approach to care, as is the philosophy of OT theory (Cole & Tufano, 2008) and scope of practice (American Occupational Therapy Association, 2014). Thus, this dissertation will focus on the following indicators which are commonly addressed by individuals in a non-hospitalized/non-acute setting under the care of the OT as a healthcare provider focusing on PI risk management.

1.4.1. Individualized Care and Intervention Planning

Individualized care and intervention planning involve the specific routines and activities prescribed by the healthcare professional in a direct treatment format (Kottner et al. 2018). Typically, this would consist of the intervention practices that healthcare providers actively implement on behalf of the client to reduce PI risk. These practices may include assistance in attaining pressure relieving postures, observation of at-risk skin surfaces, and the proper fitting and provision of wheelchairs and seating systems. This can also include clinician structured practices, such as consultation and proactive scheduling of follow-up outpatient visits for reassessment of equipment (Clarkson, et al 2019).

1.4.2. Instruction and Support for Repositioning and Documentation

Education and training of a patient and their care team can promote successful carry-over of pressure prevention practices beyond the direct care of the clinician. This process requires that the client and caregivers receive the education, and actively take on the responsibility of putting those practices into place, particularly for patients living in the community where many contextual barriers and facilitators may exist (Kottner et al., 2018).

Strict repositioning schedules, training, education, and adaptive equipment are commonly recommended for at-risk individuals (Stinson, Gillan, & Porter-Armstrong, 2013). Assistive technologies, such as motorized chair tilting systems, and caregiver education to assist with pressure relief management must be implemented among individuals with limited ability to perform their own weight shifts. This level of greater interdependence on others and on equipment adds an additional layer of complexity to PI management (Cogan, et al, 2017).

1.4.3. Availability and Application of Pressure Redistribution Devices

This study places emphasis on the role wheelchair seating plays in PI prevention. In order to manage PI risk, these devices should optimally be designed to provide well-distributed weight bearing postures, comfort, and fit for an individual's physical characteristics. This is a primary area of focus for the OT, in all stages of wound care, and is the central theme of this dissertation (Kottner et al., 2018).

1.5. Objectives and Analytical Approach

1.5.1. Paper One Objectives: Facilitators and barriers of adherence to pressure injury prevention among wheelchair users with upper motor neuron lesions.

The aim of Paper One is to provide an overview of pressure injury prevention programs and guidelines, and an analysis of the literature describing the facilitators and barriers involved

in PI prevention among individuals with upper motor neuron lesions. This paper consolidates the evidence on pressure management practices in this population.

1.5.2. Paper Two Objectives: The effectiveness of wheelchair cushions in reducing pressure injuries: a systematic review

The aim of Paper Two is to describe the features, design and materials of commercially available off-the shelf seat cushions, and to review studies of their pressure relieving characteristics, and overall effectiveness in reducing PIs. Search terms are identified, including inclusionary and exclusionary criteria, and a Prisma flow chart of results are provided. Results are displayed in an evidence table including descriptors such as study design, participants, cushion design/material, outcomes, and biases. Pressure relieving characteristics of the various cushion designs are analyzed, summarized and synthesized, with recommendations for best practice.

1.5.3. Paper Three Objectives: Efficacy of a novel unloaded shape capture method for custom-contoured seating

The aim of Paper Three is to report on a one subject pilot study conducted by this student researcher that tested an innovative custom-contoured seating shape capture method. The pressure-relieving and support characteristics of a cushion designed using an unloaded shape-capture method was compared to off-the-shelf pressure relieving cushions. The methods of this pilot trial are described, and the outcome are analyzed and summarized through descriptive statistics, including peak pressure index, average pressure and surface contact percentage for each cushion. This analysis also includes the participant's perception of postural support.

1.6. Scope and common themes of the study

Paper One lays a foundation of knowledge in regard to what is known about pressure injuries from a physiological perspective and the commonly prescribed prevention practices. This paper explores and analyzes the literature in regards to the facilitators and barriers to these practices with the purpose of informing best clinical practices for individuals with upper motor neuron lesions which is presently lacking in the literature. Paper Two proposes evidence-based best practices in the selection and utilization of wheelchair seating systems, based on a systematic review of studies that have compared these systems. Paper Three reports on the outcomes of an innovation in wheelchair seating design intended to accurately capture body shapes for reduced PI risk. Combined, these papers focus on one of the key problems associated with the seating needs of individuals with upper motor neuron lesions related mobility impairments – *pressure injury prevention*.

1.7. Problem Statement

PI prevention and treatment puts a tremendous strain on patients, caregivers and healthcare providers, while significantly impacting quality of life (Al Mutairi & Hendrie, 2018). PIs are also one of the highest sources of medical lawsuits, second to wrongful death (Krasner, 2009). PI risk among wheelchair users impacts the ability to remain mobile and functional while participating in activities and occupations of daily living. No one support surface or prevention measure can completely prevent the development of PIs (Christensen et al., 2014). The pressure relieving capacity of seat cushions, the design and material characteristics associated with improved pressure relief, and understanding the facilitators and barriers of adherence to prevention measures are not well documented in the literature for those with upper motor neuron lesion related mobility impairments. Adding to this knowledge base may help to address PI risk and improve quality of life.

1.8. Research Questions

The following chapters consist of three papers presented individually, and include a literature review, theoretical framework, methodology, results, and discussion for each. The following research questions will guide the development of each paper.

1.8.1. Paper One Research Question

What facilitators and barriers impact adherence to pressure injury reduction practices, specifically seating assessment, and skin protection behaviors, among wheelchair users with upper neuron motor lesions?

1.8.2. Paper Two Research Question

What features of wheelchair cushions most effectively address pressure injury risk?

1.8.3. Paper Three Research Question

Does a cushion designed using the direct unloaded shape capture method provide improved pressure relief compared to off-the-shelf pressure relieving cushions?

1.9. Summary

While these are separate papers with the intention of dissemination in isolation of each other, they are also inherently connected, as they address the role wheelchair seating systems play in reducing PI risk. Each paper will focus on a different aspect of this role, while emphasizing: (a) principles for populations with quadriplegia and upper motor neuron lesions, (b) a review of wheelchair cushion pressure relieving capacities and (c) a pilot study of an innovation in custom contoured shape capture methods. The intention of these papers is to help inform clinical practice, while also illuminating future research needs.

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2. Research Paper One. Facilitators and Barriers to Pressure Injury Prevention Among Wheelchair Users with Upper Motor Neuron Lesions

2.1. Introduction

This paper seeks to describe the unique facilitators and barriers to pressure injury (PI) management in relation to the diagnoses and symptoms relevant to severe upper motor neuron lesions (UMNLs), a population underrepresented in pressure injury research. This will include a description of UMNLs, etiology of PIs, and general clinical approaches to PI management for wheelchairs and seating. A review and analysis of the literature has been conducted to include research between 2010-2020, guided by the research question: *What facilitators and barriers impact adherence to pressure injury reduction practices, specifically seating assessment and interventions, and skin protection behaviors, among wheelchair users with quadriplegia or upper motor neuron lesions?* The results highlight aspects of self-care, positioning, and seat tilt and recline parameters that are unique to this population.

2.2. Background

A majority of PI related research is focused on the spinal cord injury and elderly populations, while individuals with upper motor neuron lesion (UMNL) related diagnoses, such as cerebral vascular accident (CVA), cerebral palsy (CP), traumatic brain injury (TBI), and neurodegenerative disorders (multiple sclerosis, amyotrophic lateral sclerosis, etc.) are greatly underrepresented in the literature. Emos and Agarwal (2020) describe upper motor neurons as those that initiate and modulate movement. These neurons have cell bodies primarily located in the precentral motor cortex, premotor area, supplementary motor area, primary somatosensory

cortex, and superior parietal lobe. The axons of the upper motor neurons descend through the midbrain, pons, medulla and down the spinal cord, where connections to the lower motor neurons are made. When compared to lower motor neuron injuries such as spinal cord injuries, those with UMNLs present with differences in symptoms, such as generalized muscle weakness, spasticity, clonus, and hyperreflexia while those with lower motor neuron lesions such as spinal cord injuries typically have more focal and less generalized symptoms (Emos & Agarwal, 2020). Thus, research in the area of PI management particularly in terms of wheelchair seating and cushions should be targeted to the unique needs of this population.

In the United States there are an estimated 3.6 million wheelchair users over the age of 15, according to research conducted in 2008, the year for which there is latest prevalence information available (U.S. Census Bureau, 2010). It is not clear how many more under the age of 15 use wheelchairs, however 2.6 million children under the age of 15 have a 'severe disability', which could include individuals with UMNLs. For example, more than 30% of individuals with cerebral palsy have significant or complete ambulation impairment (Christensen et al., 2014) and may need a manual wheelchair or power wheelchair to get around. Individuals with UMNLs are often at risk for developing pressure injuries (PIs) due to impaired sensation, inability to reposition themselves, nutritional deficiency, and cognitive impairment (Freundlich et al., 2017). The disability groups with the highest rate of PI prevalence include Alzheimer's disease, cerebral palsy, hemiplegia, multiple sclerosis, paraplegia/quadriplegia, Parkinson's disease and spina bifida (Sprigle et al., 2020).

A PI refers to the damage occurring on weight bearing skin underlying a bony prominence. The extent of damage can range from skin redness, to full tissue deterioration where the underlying structures, such as bone, are visible. This injury to the skin occurs most

commonly as a result of pressure, friction, shear forces or any combination of these (Al Mutairi, & Hendrie, 2018). When these biomechanical factors co-exist with declining health conditions or chronic illness, such as those experienced by the elderly or severely disabled, the risk for developing a PI increases drastically (Bauer, 2012).

PIs are most commonly classified by stages of severity. Stage 1 is characterized by non-blanchable erythema, in which the skin is intact with localized redness over a bony prominence. Stage 2 ulcers are characterized by partial thickness ulceration, with no tissue slough (a yellowish/greyish fluid). Stage 3 ulcers involve full-depth ulceration where subcutaneous tissue may be visible. Slough may be present, but not enough to prevent a clinician from determining the depth of tissue loss. Stage 4 is similar to stage 3, with the distinction marked by inclusion of visible underlying bone, muscle, tendon or ligaments. Unstageable ulcerations are those in which depth of tissue damage cannot be determined due to slough, which usually suggests the damage is full thickness (stage 3 or 4). A less severe unstageable ulceration is characterized by purple or maroon colored tissue which may indicate deep tissue injury. This condition can quickly progress to more severe stages (Bauer, 2012).

PIs are not unique to any one condition or diagnosis. PI prevention has been commonly studied and well documented in the SCI and elderly populations. Studying the SCI population allows researchers to control for a complex array of comorbidities, as this population can be generally healthy aside from injury-related impaired mobility and lack of sensation. This can help identify which preventative methods, behaviors, factors, and technologies are most effective for PI management (Mak et al., 2010). However, individuals with UMNLs may present with a greater array of clinical complexities impacting pressure injury risk, which poses a challenge to

describe systematically. Due to these increased complexities, PI prevention within this population must include a whole systems approach (Freundlich et al., 2017).

2.2.1. Interventions for Pressure Management

Chisholm and Yip (2018) describe individuals who are at risk for developing a PI, but never have acquired one, as *pre-wound*. The goal is to prevent PI from ever occurring. The system for staging of PIs does not allow stages to be retracted even when a wound has ‘healed’, since a healed wound is at increased risk for reoccurrence. A healed PI continues to be classified as a PI, thus, prevention is a primary goal of seating intervention. According to Chisholm and Yip (2018), management protocols for at-risk individuals may consist of the following:

Interprofessional team management. An interprofessional collaborative PI management team should consist of the OT or physical therapists (PT), wound nurse, and client. Theoretically, the role of these individuals shifts based on the wound phase. During the *pre-wound phase*, the OT and PT play a primary role in prevention while the nurse and client contribute less. During the *wound phase* the wound nurse takes on the most significant role in remediation. In the *post wound phase*, the OT, PT and client play the major role as the focus shifts toward collaborative preventative measures (Chisholm & Yip, 2018).

Specialized training of team members. Methods used by clinicians to address PIs can consist of assessing, recommending, and fitting of seating devices, as well as addressing positioning, weight shifting education, and collaboration with other professionals (Stinson et al., 2013). Team members with specialized training in wound care and support surface technology play critical roles in terms of education, assessment and application of preventative measures and equipment. A clinician specializing in seating systems is experienced in analyzing the anatomical and biomechanical principles related to wheelchair seating and serves as the user-device

interface expert, with a specific focus on function, participation, and independence. This team should also engage a knowledgeable equipment vendor (Arledge et al, 2011).

Comprehensive seating assessment, including skin health factors. The seating assessment is a multifaceted process in which the clinician attempts to assess PI risk, create a solution to addressing the wound or risk, and implement the device and program. According to Minkel (2018) this process consists of: (a) the client and caregiver interview, (b) understanding the person's current mobility status/mobility assessment, (c) assessment of sitting balance/hand-supported sitting, and (d) skin inspection and assessment for risk of skin breakdown. Minkel (2018) also describes the skin health factors of relevance to managing PIs as the assessment of *skin integrity, impaired sensation, and impaired mobility*, as well as other risk factors including nutrition.

Seating interventions. Seat cushions come in various shapes, designs, and materials, all of which serve different purposes. While this paper will not describe these variations in seating systems, it is important to note that matching the right system to the client's specific needs plays a critical role in the PI management process. According to Minkel (2018), the seating intervention consists of (a) trialing of potential solutions, (b) recommendation of seating and mobility products, (c) training, and (d) follow-up/determination of outcomes.

A 24-hour positioning approach. Wheelchair users, particularly those with impaired sensation, are typically prescribed weight-shifting/repositioning routines on a regular schedule, such as push-ups, forward or lateral leans, or the reclining of a tilt-in-space wheelchair system, depending on the individual's ability. The purpose of these practices is to decrease the risk of pressure injuries (PIs) by promoting vascularization of tissues experiencing extended compression and deformation as a result of prolonged sitting (Stinson et al., 2013).

Skin observation as part of physical assessment. Skin inspection is a critical part of wound care, as it is critical for prevention, early and ongoing intervention, medical documentation and insurance reimbursement (Luboz, 2018). Individuals with functional upper extremity and trunk control are typically capable of performing this task with the use of adaptive equipment, such as skin inspection mirrors. However, individuals with severe UMNLs may require caregiver assistance in order to perform this task.

Use of outcome measures and screening tools. Effective intervention requires clinicians to perform a clinical risk assessment and the use of standardized risk assessment scales. The most common is the Braden scale (Iranmanesh et al., 2012), often used in hospitals and rehabilitation centers. Sensory perception, moisture, activity, mobility, nutrition, friction and shear are measured on a scale of 1-4 based on specific descriptors for each category (Iranmanesh et al., 2012). An overall score of less than 10 constitutes severe risk, 10-12 high, 13-14 moderate, 15-18 mild, and greater than 18 is no risk. While the Braden scale has demonstrated acceptable validity and reliability (Jin et al., 2015), it has limited predictive capacity due to the array of contextual, behavioral, anatomical and physiological contributors to PIs that are not tracked by the scale (Reenalda et al., 2009).

Use of specialized tools, such as pressure mapping. Pressure mapping systems can be integrated into hospital and rehabilitation facility screening procedures as a means of identifying PI risk and mitigating this risk through identification of support surfaces that appear to provide adequate pressure distribution (Kottner et al., 2018). This system provides a visual depiction of the interface pressures experienced at the surface of the tissue, which provides important information in seating system assessment and can be useful as a feedback system to teach effective weight-shifting strategies (Chisholm & Yip, 2018).

Teaching the client critical skin protection behaviors. Providing the client with general and specific prevention techniques is critical for all stages of wound care including pre- and post-wound care. These processes include regular *skin checks*, effective and rigorously adhered to *weight shifting* routines, proper *maintenance of equipment*, and *awareness of local health care resources* (Chisholm & Yip, 2018). A systematic review by Cogan, et al. (2017) suggests mixed outcomes on current educational skin protection programs for reducing pressure ulcers among individuals with spinal cord injuries. This review consisted of three randomized control trials and two quasi-experimental designs with a total of 513 participants, mostly with spinal cord injuries. Only one study in this review included individuals with UMNLs, specifically multiple sclerosis, in addition to spinal cord injuries (Houlihan, et al., (2013). Results suggested there was statistical significance in increased duration of prolonged PI prevention, however baseline equivalence between the education and control group could not be established (Cogan, et al., (2017).

However, highly structured and institutionally implemented PI prevention programs appear to have greater efficacy. One study, most applicable to the present review, consisted of an institutionally implemented educational program for individuals with developmental disabilities residing in a state institution. The nurses were trained in pressure ulcer prevention techniques and principles resulting in an increase from 50% to 100% accuracy on pre- and post-knowledge-based tests respectively. Furthermore, PI occurrence decreased to zero in the weeks following the education program, resulting in the program's implementation as part of new-staff and ongoing training (James, 2017).

2.3. Purpose

For individuals with quadriplegic SCI or UMNLs, managing PIs requires a holistic and systems intervention approach consisting of on-going assessment, training, education, use of

equipment, and self-care techniques (Chisholm & Yip, 2018). Preventing PIs is a lifetime commitment fraught with more nuanced complexities due to changing cognition, tone imbalance, deformity, posture, and positioning challenges. However, presently, there is limited research on specific facilitators and barriers for pressure relief among those with UMNLs (Freundlich et al., 2017). The purpose of this review is to report on the available evidence regarding PI management for this population, guided by the research question: *What facilitators and barriers impact adherence to pressure injury reduction practices, specifically seating assessment and interventions, and skin protection behaviors, among wheelchair users with quadriplegia or upper motor neuron lesions?* The aim is to consolidate what is known about the unique characteristics of those with quadriplegic SCI and UMNLs, and fill a gap in the PI management knowledgebase for this specific population. This information may help to inform clinical practice, provide recommendations, and highlight gaps for future research.

2.4. Theoretical Framework

In the rehabilitation sciences, the Biomechanical frame of reference may be used to describe the anatomical and physiological causes of PIs (Cole & Tufano, 2019). This framework links principles of human physical activity to function. It explains how the structural components of muscle and bone lead to postural support, positioning, and movement (Cole & Tufano, 2019). While PIs can occur in any position and skin surface, they are particularly problematic in prolonged seated postures, as gravitational forces are isolated to small surface areas of the buttocks, leading to tissue damage (Sonnenblum et al., 2015). PIs may be further exacerbated by friction, tissue deformation, and certain health conditions (Bauer, 2012). Prescribed pressure relieving practices, adhered to consistently, promote tissue health and prevent vascular

compression. This review will explore evidence for the facilitators and barriers that impact the clinical efforts of maintaining this physiological balance.

2.5. Methods

A concept map was created to identify terminology that will link what is known regarding pressure relieving management and the context specific application of these practices to the population with UMNLs. These terms were used to search the literature to identify the unique facilitators and barriers to this population. The literature was searched through the PubMed/MEDLINE database, including the Medical Subject Headings (MeSH) system in PubMed to identify related terms.

- The following terms included the Boolean operator ‘*or*’ during the search process: *Upper motor neuron injury, neurodegenerative, neurological impairment, neuromotor impairment, quadriplegia, tetraplegia, cerebral vascular accident, cerebral palsy, traumatic brain injury, amyotrophic lateral sclerosis, multiple sclerosis.*
- These terms were combined with the following set of terms through the Boolean operator ‘*and*’, and will include the operator ‘*or*’ during the search process: *positioning, seating, wheelchairs, pressure ulcers, pressure injuries, skin care, caregiver training, self-care, skin factors.*
- The following terms were excluded from the search results with the Boolean operator ‘*not*’: *elderly, hospitals, mattress, surgery.*

2.5.1. Inclusionary Criteria

- Related to wheelchair users with severely limited mobility impairments such as those resulting in quadriplegia in which all extremities are affected.
- Related to pressure relief

- Related to seating systems
- Articles published in English only
- Research related to factors:
 - Seating assessment and intervention
 - Effective positioning
 - Caregiver and patient training
 - Skin observation
 - Skin protection factors and behaviors

2.5.2. Exclusionary Criteria

- Research published prior to 2010
- Research related to elderly individuals, as this can confound the variables of interest
- Research related to spinal cord injury, as this population can be mostly healthy, independent and lack the needs associated with custom contoured seating such as poor trunk control and deformities.

2.6. Results

A review of the search terms resulted in 5589 journal articles published between 2010 and 2020. The titles were reviewed resulting in 52 abstracts screened, and 36 selected for full article review. Of these 36 articles, only 15 met inclusionary criteria of the present study and research question, and are included for review (see Table 2.1). Few articles actually studied individuals with quadriplegia or upper motor neuron injuries. The remaining studies have been carefully selected as the present author believes they provide important information relevant to the research question even though they may have consisted of able-bodied participants. These

limitations in generalizability will be considered in the discussion section. These studies have been categorized into the following areas: a) self-care, b) positioning, c) tilt/recline.

Table 2.1.

Evidence table: Studies included in quantitative and qualitative synthesis

Lead Author (date of pub.)	n	Diagnosis	Main Observations	Level of Evidence
Agustsson (2017)	714	Adults with CP	22% of individuals with CP who are classified at GMFCS level V present with asymmetrical limited flexion at the hips (< 90°).	IV
Chen (2014)	13	Quadriplegia and paraplegia SCI	Significant decreases in pressure occurs at angles of 10 degrees of recline and 35 of tilt.	III
Giesbrecht (2011)	18	Quadriplegia and paraplegia SCI	A minimum of 30 degrees is needed for significant pressure reduction, with fixed recline.	III
Jan (2010)	11	Quadriplegia and paraplegia SCI	35° tilt-in-space combined with 10° recline, and all 3 tilt-in-space angles combined with 30° recline, showed a significant increase compared with baseline sitting (P<.05).	III
Jan (2013)	20	Quadriplegia and paraplegia SCI	A larger angle of tilt-in-space and recline is needed to improve muscle perfusion compared with skin perfusion. A position of 25 degrees tilt-in-space combined with 120 degrees recline is effective for increasing muscle perfusion at the ITs.	III
Kobara (2012)	11	Able-bodied males	Return to upright from a recline position significantly increases shear forces applied to the buttocks.	III
Lampe (2010)	72	Cerebral Palsy	Accommodation of deformities, obliquities and asymmetries is preferable and reduces pressure, and pain when compared to corrective seating.	V

Lead Author (date of pub.)	n	Diagnosis	Main Observations	Level of Evidence
Latimer (2014)	20	SCI	Illness, cognitive impairment, and disability were deemed barriers to PI prevention, causing these patients to have a passive role.	Qual.
Li (2017)	16	Able-bodied	Additional lumbar support, when added to a recline and tilt seating system were the most effective for pressure relief as these supports unloaded the weight off of the ITs and sacrum.	III
Li (2019)	15	Able-bodied	Additional lumbar and femur support, when added to a recline and tilt seating system were the most effective for pressure relief as these supports unloaded the weight off of the ITs and sacrum.	III
Saquette (2018)	63	Cerebral Palsy (children)	Implementation of an educational program for the primary caregivers of children with CP showed statistically significant improvements in self-care and mobility, compared to a conventional rehabilitation program with no caregiver-education component.	I
Sleight (2019)	75	SCI	Qualitative interviews of factors that may prevent incidence of PI resulted in eight themes, including: meaningful activity, motivation, stability/resources, equipment, communication and self-advocacy skills, personal traits, physical factors, and behaviors/activities	Qual.
Tasker (2014)	30	Able-bodied	Custom contoured seating is more effective at pressure relief when compared to off-the-shelf contour and baseline flat foam.	III

Lead Author (date of pub.)	n	Diagnosis	Main Observations	Level of Evidence
Ukita (2020)	28	Stroke	Using a backrest with progressive recline of 100-110-120°, and a midline corrective pelvic-lumbar strap increased midline positioning during functional activity.	III
Zemp (2019)	20	Able-bodied	Using minimal tilt and recline angles promotes increased use, as opposed to large angles. Significant recline angles also significantly reduce pressure, but introduces significant shear forces.	III

Note. Table consisting of lead author, date of publication, sample size, sample diagnosis, main findings, and level of evidence. Levels of evidence based on: Arbesman, M., Scheer, J., & Lieberman, D. (2008). Using AOTA's critically appraised topic (CAT) and critically appraised paper (CAP) series to link evidence to practice. *OT Practice*, 13(5), 18–22.

2.6.1. Self-care

One of the PI management barriers for individuals with complex physical disabilities including those which often have cognitive impairment, illness, and severe disability relate to self-care. This population often requires the assistance of caregivers over their own PI management regimen which leads to limited autonomy. A qualitative study by Latimer et al. (2014) included interviews with 20 recently hospitalized adults with unspecified disabilities and presenting with PIs. The participants described frustrations with inability to participate or make decisions regarding self-care, lack of knowledge about PI, costly PI prevention, difficulty accessing PI prevention information, and struggling to get PI prevention care, among others. In a control trial conducted by Saquetto et al. (2018) an educational program for primary caregivers of 63 children with cerebral palsy was implemented in the areas of self-care, mobility,

gross-motor function and social function, and compared to a conventional rehabilitation program where caregivers did not receive education. While not specifically addressing PIs, the caregivers receiving the educational program performed better in assisting with the areas of self-care ($p = .017$) and mobility ($p = .002$) on the Pediatric Evaluation of Disability Inventory: Caregiver Assistance Scale (PEDI-CAS) when compared to the control group (Saquette et al., 2018).

A qualitative study of 75 SCI participants sought to understand what factors were protective against PI by comparing 50 who did not develop a PI to 25 participants who did. The resulting themes of protective factors included having meaningful activity, motivation to prevent negative health outcomes, stable housing, caregiver and financial support, access to equipment, communication and self-advocacy behaviors, personal traits, and physical factors. Behaviors which include proactive response to health care issues, health promoting behaviors, and knowledge and skills appears to be a critical aspect of PI prevention (Sleight et al., 2019).

2.6.2. Positioning

Increased muscle tone, spasticity and postural deformities can significantly impact positioning needs of those with UMNLS. Four articles included in the present review address positioning, most specifically in regard to the asymmetrical hip flexion common in those with cerebral palsy (CP). Agustsson et al. (2017) suggests 22% of adults with CP, out of a sample of 714, presented with asymmetrical hip flexion of less than 90 degrees unilaterally. These individuals were more likely to present with pelvic obliquity (OR 2.6, 95% CI:1.6–2.1), asymmetrical trunk (OR 2.1, 95% CI:1.1–4.2), scoliosis (OR 3.7, 95% CI:1.3–9.7), and windswept hip distortion (OR 2.6, 95% CI:1.2–5.4), all of which can negatively impact PI management.

Studying a similar group of 72 children aged 2-20, Lampe and Mitternacht (2010), further describes the challenges of providing this population with seating systems to correct deformities while also providing pressure relief, which are often competing goals. The authors describe this process as one in which providing sufficient postural support in order to promote upright positioning and function competes with effective pressure relief, particularly in a population with inability to reposition themselves, and often lack the cognitive or communication skills to direct caregivers or control technology for making positional adjustments. The authors describe and advocate for the use of soft seating surfaces in order to promote accommodation and pain reduction, but also using pressure mapping to assist in the clinical decision-making process in which a fine balance between postural support and pressure relief are optimized while minimizing the negative impacts (Lampe & Mitternacht, 2010). This study does not provide statistical inferential conclusions; rather, several case examples are provided with descriptive data illustrating how pressure mapping was utilized to help make clinical decisions for reduction of pain and selection of appropriate seating surfaces with individuals with complex seating needs.

A different means of approaching complex positioning and pressure relieving needs is through the use of highly contoured seating or custom-contoured seating in which seating systems are custom fabricated to match the user's exact shape. Tasker et al. (2014), compared the pain relieving and pressure relieving capacity of three types of seating systems all composed of the same type of foam material. The comparisons consisted of a custom-contoured seat cushion, an off-the-shelf design contoured cushion, and a flat baseline cushion. Results suggest the custom-contoured shape provided the best pressure relief and comfort, signifying the importance of cushion shape beyond material construction.

Post-stroke (CVI) individuals also present with positional challenges that impact posture and PI risk. Two separate studies describe those with flaccid hemiplegia as demonstrating greater pressure in the ITs and sacral areas when compared to those with spastic hemiplegia and healthy controls, thus emphasizing the need for increased focus on the pressure relief of those with flaccid muscle tone (Huang et al., 2011; Li et al., 2013).

In a within-subjects comparison study of 28 participants post CVI, Ukita et al. (2015) noted the tendency of this population to lean onto their affected side during sitting, placing increased pressure on the ischial tuberosities (ITs) of the affected side. The authors sought to compare the change in postural alignment and seat pressure when comparing sitting in a wheelchair with a standard backrest set to 96 degrees of recline, to that of a modified backrest in which the pelvic lumbar, lower thoracic and upper thoracic recline was set to 100°, 110° and 121° respectively.

Furthermore, this experimental backrest provided further lateral support of the pelvic lumbar region in the form of a pelvic-lumbar slackened strap (similar to a contoured backrest), with the purpose of promoting midline alignment of the lower trunk. Neither backrest perfectly corrected postural alignment, however, the experimental backrest with increased progressive recline and pelvic lumbar strap promoted increased return to midline and decreased asymmetry in seat pressure distribution. This data was collected while participants performed a simulated functional upper extremity activity requiring reaching, starting from the non-affected to the affected side and back to starting position (Ukita et al., 2015). While this study focused on the effects of a novel type of backrest, the improved results of increased recline on decreasing pressure relief is similar to what other research in this area suggests, as is described in the next section.

2.6.3. Tilt/recline

A large portion of the present search results are focused on the optimization of wheelchair tilt and seat to back recline angles needed for optimal pressure relief. While these studies used varying tools to measure pressure relief, the results appear to mostly corroborate the general outcome. Both tilt and recline play a critical role in pressure relief particularly for individuals unable to perform their own weight shifting routines. By using *skin perfusion* (microcirculatory blood flow) as a means to determine ‘effective’ pressure relief, Jan, et al. (2010) reported a minimum recline angle of 100° was needed when paired with at least 35° of tilt; whereas at least 120° of recline was needed when using as little as 15° of tilt. In a later study, Jan, et al. (2013) measured skin *and muscle perfusion* citing the added importance of muscle perfusion in outcome measures of pressure relief. The results indicate greater levels of tilt (25°) and recline (120°) significantly increasing muscle perfusion over baseline sitting, which is more than what is needed for skin perfusion (see Table 2.2).

In addition to recline, the addition of lumbar and femur supports to the seating system has been studied among healthy participants. These supportive devices appear to help redistribute the weight of the participants away from the ischial tuberosities. While not statistically significant, the combination of a lumbar and femur support provided the lowest IT pressure interface, with any amount of recline (Li et al., 2017; Li et al., 2019).

Zemp et al. (2019) suggest any combination beyond 15° tilt and 5° recline substantially (although not statistically significant) reduces seat interface pressure. They emphasize the reality that wheelchair users seldom take the time to regularly conduct periodic ‘full’ tilt and recline weight shifting regimens. The authors suggest, by studying the impact minimal tilt and recline angles may have on pressure reduction, may provide useful information for wheelchair use in a

Table 2.2.*Recline and tilt angles for significant pressure relief over baseline*

Lead Author (date of pub)	<i>n</i>	Recline + Tilt angles *	Measure/Tool
Chen (2014)	13	10° + 35°	Pressure map
Giesbrecht (2011)	18	no recline + 30°	Pressure map
Jan (2013)	20	30° + 25°	Muscle perfusion using near- infrared spectroscopy
Jan (2010)	11	10° + 35° 30° + 15°	Skin perfusion using Laser Doppler flowmetry
Ukita (2015)	28	20° (mean) + no tilt	Pressure map
Zemp (2019)	20	5° + 15°	Pressure map and skin perfusion using Laser Doppler flowmetry

Note. *Minimally significant recline + tilt angles over baseline.

realistic context. For example, if a wheelchair user is able to maintain a 20° tilt and 10° recline throughout a significant portion of the day, this may promote improved PI management as compared to suggesting intervals of 45° of tilt at many intervals, which is a non-functional position for most wheelchair users. Zemp et al. (2019), also suggest that significant levels of recline alone are capable of significantly reducing pressure, but this comes at the expense of shear forces, particularly when returning to an upright position.

Conversely, Giesbrecht et al. (2011), found among a group of 18 participants with paraplegia and quadriplegia a minimum of 30° of tilt is needed to significantly reduce pressure

when not combined with additional recline. Furthermore, the authors found increased pressure on the ITs and sacrum during minimal levels of tilt, describing the only benefit being postural support. There were no differences in the reaction to pressure among the different participant SCI levels. While these findings may appear contradictory to the study by Zemp et al. (2019), it highlights the importance at least minimal amounts of recline play in the process of redistributing pressure away from the ITs and sacrum when combined with tilt. The negative impacts of shear can negatively impact any benefits of using significant amounts of recline as a sole means for pressure relief and thus should always be paired with tilt.

2.7. Discussion

A common approach to PI management among wheelchair users is adoption of routine weight shifting in order to provide periodic pressure relief. However, individuals with quadriplegia or UMNLS characterized by severe motor impairments will have limited or complete inability to perform weight shifting manually due to lack of neuromotor control of the upper extremities (Emos & Agarwal, 2020). Power tilt or recline seating is a feature commonly added to power wheelchairs to provide users a means to perform routine tilting in order to temporarily decrease the pressure on the buttocks. One of the issues in the application of power tilting features is that this technology is often limited to power wheelchairs. However, those with cognitive impairments are rarely prescribed power wheelchairs since their use requires safety awareness, navigational concepts, and impulsivity control. These individuals are often dependent upon manual wheelchairs propelled by caregivers, leaving them with little or no volitional mobility options at all (Abbaskanian et al., 2015). Thus, cognitive impairment can be a barrier to pressure relief management.

As described by Agustsson et al. (2017), individuals with CP often present with asymmetrical hip flexion of less than 90° unilaterally. This suggests many individuals with CP are unable to comfortably reach the 90° hip flexion position, particularly if seated in a wheelchair with a seat-to-back angle set at 90°. This study also describes the increased association with pelvic obliquity, trunk asymmetry and, windswept deformities among this group when the hip flexion limitation is asymmetrical (greater on one side versus the other). What is not clear however, is whether sitting in a device angled at 90° over many years contributes to trunk asymmetries, pelvic obliquities and windswept deformities, or if these deformities are merely a result of the same muscle tone imbalances causing the limited hip flexion. As trunk asymmetries, pelvic obliquities, and windswept deformities can lead to challenges in providing this population with effective pressure relief seating surfaces (Lampe & Mitternacht, 2010), the association between mismatched recline angles among those with hip flexion asymmetries, and the impact on spinal structural deformities is worth further investigation. A causal relationship between these constructs may suggest clinical implications for seating system professionals to take a more active stance in accommodating the asymmetry. If the relationship is correlational as opposed to causal, then accommodating hip flexion asymmetry may be solely applied for the purpose of comfort and pressure relief. Nonetheless, increased amounts of recline must be considered carefully and used sparingly, preferably in combination with tilt so as not to introduce dangerous levels of shear.

In regard to the actual seating surfaces, results of the study by Lampe and Mitternacht (2010), and Tasker et al. (2014) appear contradictory at first. Lampe and Mitternacht promote the use of soft surfaces over firm ones, whereas Tasker et al. (2014), promote the use of custom-contoured cushions which is essentially a firm surface. However, custom contoured cushions are

intended to provide accommodation for postural deformities by providing high levels of contour and thus providing positioning support while also distributing the user's weight over increased surface area. This is essentially the same goal of providing a soft surface, which is to provide immersion to increase contact area and accommodation. The key difference is that creating a custom-contoured cushion is a more expensive and complex process than prescribing a soft off-the-shelf seating surface.

While there were no studies that described the impact of muscle tone on the impacts of seating and PI management for those with CP, Huang et al, (2011; 2013) and Ukita et al. (2015) describe post stroke patients with flaccidity as being at greater risk due to increased pressure when compared to those with spasticity. This makes sense as the rigid quality of spasticity may facilitate weight bearing onto the femurs, back and feet, while reducing weight bearing on the posterior aspect of the buttocks. What is not clear from this research however, is how spasticity may impact PI risk upon other body surface areas.

In regard to the Jan et al. (2010; 2013) studies using skin perfusion to measure pressure relief, the challenge is determining what is 'effective' pressure relief, as with any measurement outcome other than actual PI incidence effectiveness. These studies determined that certain angles of tilt and recline significantly improved perfusion over baseline, but lack evidence for what is actually needed for effective pressure relief. What determined a seat angle as 'effective' in this study, was the statistical significance largely based on sample size, alpha levels, and variance (SD), not actual PI prevention. Thus, while all non-PI incidence studies highlight the importance of tilt and recline in terms of changing the pressure at the buttock seat interface, there does not exist a specific measure for pressure prevention effectiveness. Furthermore, as is the case for much of the outcomes related to the present research study, any over-simplified

generalization should be avoided due to the unique physical neurological and musculoskeletal characteristics of each individual (Zemp et al. 2019).

The combination of results regarding hip asymmetry and benefits of recline (when paired with tilt) is that individuals with severe motor impairments are at increased risk of asymmetrical hip flexion contractures which benefit from the use of recline in order to accommodate and reduce pelvic obliquities which may reduce pressure and pain. Thus, the clinical implications of these findings suggest that therapists should take particular efforts to assess lower extremity and specifically hip flexion range of motion measurements. If flexion contractures are noted, matching the seat to back recline angle to the most contracted hip may not only increase comfort, reduce pelvic obliquity, and windswept deformities, but it is suggested by the literature to be an effective means to reduce the pressure on the ITs. However, large amounts of recline must be used with caution so as not to introduce dangerous amounts of shear at the seat, which can be minimized, to some degree, through the use of tilt.

Lastly, health promoting behaviors and self-care support play crucial roles in PI management specifically for individuals with limited physical or cognitive ability to perform independent self-care routines such as skin checks, weight shifting, repositioning, and control of devices (Latimer et al., 2014; Sleight et al., 2019). Education and training of patients and caregivers to seek medical advice as soon as issues arise, as well as promotion of regular skin checks, repositioning, weight shifting, cushion checks, and general education on the specific properties, activities, behaviors and routines appear to be essential for PI risk management, although the research is mixed regarding its effectiveness.

2.7.1. Limitations

One of the main limitations of this review is the inclusion of literature with able-bodied participants. Research with participants who represent the population of interest are increasingly scarce in this area of study due to the challenges associated with ethics board review approvals and the ethical implications of putting at-risk individuals in study conditions that may actually do harm. Studies commonly substitute able-bodied subjects for study participation with the hopes that outcomes can be generalized to the population of interest. However, individuals with severe mobility impairments are inherently different in many ways, particularly in ways that impact study outcomes. Another limitation involves the abundance of efficacy, but scarcity of effectiveness research studies. Efforts were made to search the literature demonstrating clinical effectiveness over laboratory efficacy when possible, and compromising when no other literature was available.

2.8. Conclusion

This systematic review searched the literature for research on the topic of PI prevention among wheelchair users with quadriplegia and UMNLs. Results were limited, specifically due to the unique characteristics associated with the complexities experienced by this population such as tone, deformities, and behaviors. Furthermore, much of the research available has been conducted on able-bodied participants which significantly impacts generalizability of findings. What does appear consistent throughout the results of this search is the need to perform a thorough seating evaluation by skilled and experienced clinicians in order to match the best devices, seating configurations and seating angles to the unique needs of the individual, while also providing comprehensive and ongoing self-care and caregiver training, along with resources to continue to seek health care services on an ongoing basis.

One area of consistency in terms of pressure management facilitators is the use of recline and tilt to promote effective PI relief, especially for those unable to perform independent weight shifting routines. While most studies differ in the exact prescription of what is effective pressure relieving tilt or recline angles, a common reported range is tilt angles of 25-35° and recline of 10-20°. It is also clear that large angles of recline introduces dangerous levels of shear on the buttocks, particularly when returning to an upright position. Thus, recline should be used sparingly, and in combination with tilt.

The results of this review further highlight the need for future research to help identify improved methods for PI prevention and management for populations with limited independence in self-care skills. This includes higher levels of evidence in regard to specific caregiver training and resource regimens, most effective technologies and devices for PI management, and studies of actual PI incidence and prevention effectiveness, specifically for tilt and recline as a means for weight redistribution.

2.9. References

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3. Research Paper Two. The Effectiveness of Pressure Relieving Cushions in Reducing Pressure Injury: A Narrative Review

3.1. Introduction

This narrative review seeks to gather and analyze the evidence on wheelchair pressure relieving cushions, and report on the optimal materials and designs for reducing pressure injury risk. The following research question guides this study: *Which wheelchair cushions best reduce pressure injury risk?* PIs continue to impact the health and function of wheelchairs users with significant mobility impairments. Pressure relieving cushions are typically prescribed to provide pressure relief in the pre-wound, wound, and post-wound phases. Presently, no published reviews analyze all of the commonly available cushion materials. Most comparison studies typically address a specific population such as spinal cord injury, or only a few styles of cushion design/materials. This narrative review compares interface pressure relieving capacity of all cushion materials and designs and makes recommendations for choosing the best pressure relieving cushion for wheelchair users at risk of pressure injuries.

3.2. Background

Pressure injuries (PIs) affect at least 2.5 million people in the US, with a financial impact on society estimated at roughly \$10 billion per year (Agency for Healthcare Research & Quality, 2014). PIs are a common problem among the elderly and the severely disabled, as impaired sensation and decreased mobility and positioning options can lead to increased risk. PIs are often related to health conditions, such as frailty and obesity, and neurological disorders that restrict or limit movement, such as paralysis (Padula et al., 2017). Many other risk factors increase the vulnerability of tissue damage, such as aging, smoking, poor nutrition, and diabetes as these

directly impact the ability of the tissues to remain vascularized. Biomechanical factors such as tissue thickness may also impact PI risk. For example, wheelchair users with spinal cord injury (SCI) often present with less adipose and muscle thickness between the skin and ischial tuberosities (ITs) when compared to ambulatory individuals. The ITs are the bony prominences located at the inferior surface of the ischium of the pelvis, and are common PI sites due to the pressure they place on tissues when loaded, particularly in sitting (Mak et al., 2010).

The direct ‘external’ causes of PI are typically shear, friction, and/or microclimate. *Shear* is described as the force experienced within the tissue as opposing forces move in parallel. This distortion within the tissue can damage capillaries in the vascular system. Similarly, *friction* is the force experienced by the outer layer of the skin as it slides across a surface, such as a cushion, mattress, or any other support surface (Sonnenblum et al., 2018).

Surprisingly, of these two forces it is shear that is most likely to lead to PI due to the delicate nature of the vascular system in maintaining skin tissue health. Sonnenblum et al. (2018) describe the impact of internal shear as the process of tissue deformation occurring under tissue load, met with resistance of bony protuberances. This pressure or force inflicts damage upon the complex circulatory system within the tissues, thus potentially impacting the immediate vascular system of all cells of the dermis, epidermis, subcutaneous, adipose tissue, and muscle layers (Mak et al. 2010). Furthermore, the reperfusion process in which oxygen is restored to the damaged areas results in the development of scar tissue. This scar tissue is less vascularized than healthy tissue, and thus is susceptible to future damage (Xiao et al. 2014). The third contributor is *microclimate*, which refers to the temperature and moisture balance. Both high and low temperatures can lead to PIs. Skin that is exposed to prolonged excessive moisture or dryness is

also at risk for PI. Both are somewhat linked, as too much heat causes sweating (excessive moisture), and low temperatures makes it difficult for the body to heal (Chisholm & Yip, 2018).

Prolonged sitting with insufficient weight shifting will eventually lead to devascularization in the tissue located under bony prominences. Pressure relieving surfaces can help reduce PI risk when used correctly, providing relief against severe tissue deformation and protection against friction and shear forces (Sprigle, 2011). Seat cushions are a significant method of addressing PI risk in full-time wheelchair users (Sonnenblum, et al., 2016). Cushions come in many shapes, materials, and designs, but determining which cushion provides optimal pressure relief based on the research evidence is challenging. Different researchers use different metrics to determine efficacy and seldom use actual pressure injury incidence as an outcome measure.

3.3. Methods

The PubMed/MEDLINE, CINAHL Complete, Cochrane library, and OT Seeker databases were used to identify studies that meet inclusionary and exclusionary criteria using the following search terms and Boolean operators:

- *Pressure ulcer 'or' pressure injury support surfaces*
- *Pressure ulcer 'or' pressure injury interface*
- *Seating 'or' cushion 'and' pressure ulcers 'or' injuries*
- *Custom contoured cushion*
- *Off-loading cushion*
- *Pressure relieving cushion*

3.3.1. Inclusionary and Exclusionary Criteria

This narrative review includes studies published in English-language peer-reviewed journals on or after 2005 that involve methods and outcomes that address measures of pressure relief, such as pressure mapping, Magnetic Resonance Imaging (MRI) or Finite Element (FE) modeling for seating systems such as those used in wheelchairs. Additionally, text book and peer reviewed journal articles were used to substantiate background information on PI prevention, cushion characteristics, and risk factors often not described in cushion comparison studies.

3.3.2. Analysis

Search results are shown in a PRISMA flow diagram (see Figure 3.1), and reported in an evidence table with the following information: author, year, participant diagnosis, main observation/outcomes, cushion design/materials, and level of evidence. Results are summarized and synthesized through an analysis of participants, presence of bias, and strength of the study design. Furthermore, an analysis of the measurement tool and outcomes measures as possible moderators may help to elucidate patterns in the discrepancies of cushion performance throughout the literature.

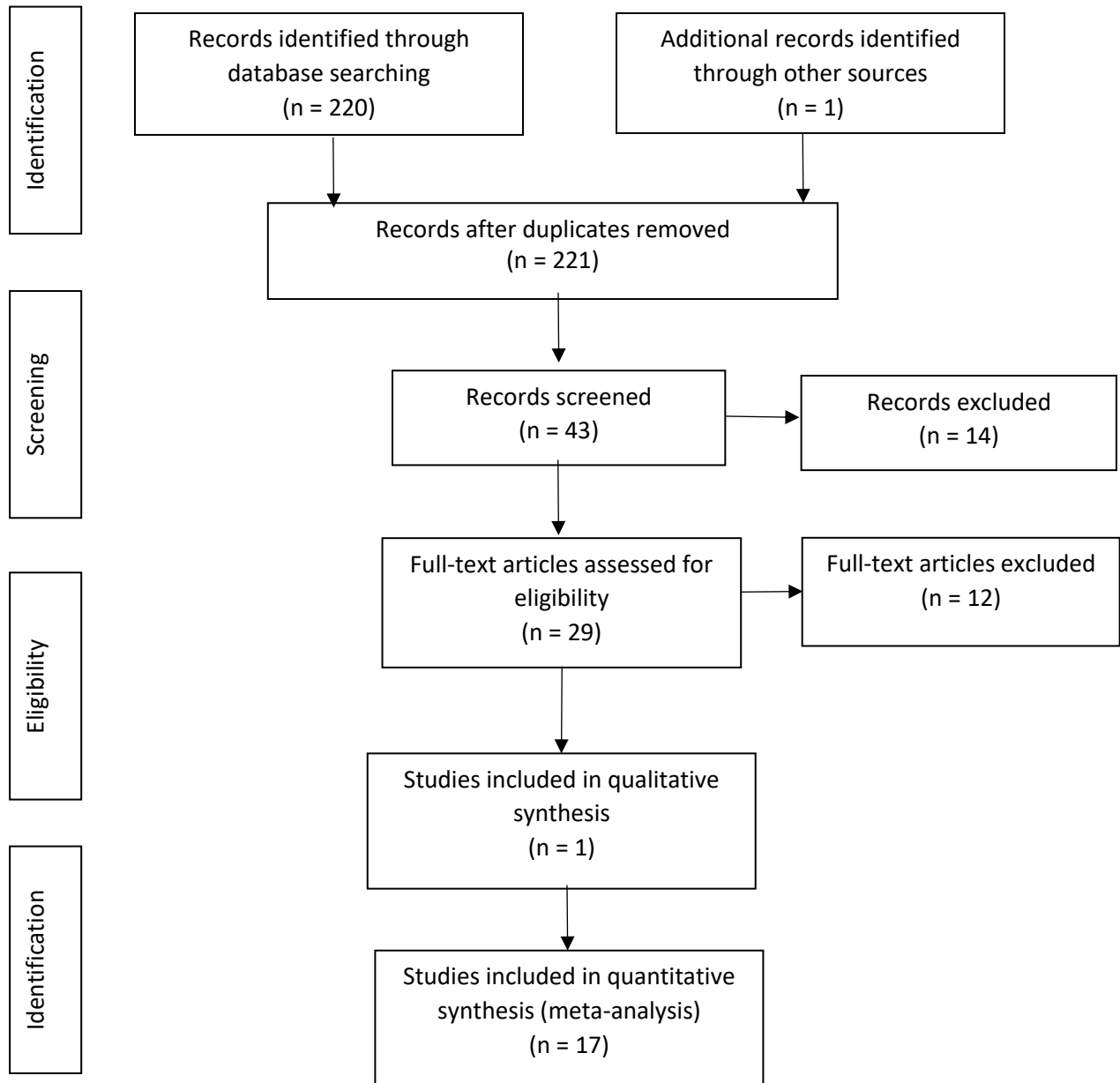
3.4. Theoretical Framework

The Human Activity Assistive Technology (HAAT) model (Cook & Polgar, 2015a) is commonly used in guiding the application of assistive technology and will serve as the theory for this review. This theory borrows from the ecology of occupational therapy model known as Person, Environment, Occupation, Performance (PEOP), and considers the interaction among a person's abilities and interests, their preferred activities, the tools that may enable improved functional performance of a particular activity, and context (Bass et al. 2015).

In the realm of wheeled mobility, the most obvious context factor is the accessibility of the physical environment. While wheeled mobility devices assist the individual in accessing

Figure 3.1.

PRISMA Flow Diagram of Study Selection.



Note. Flow diagram of articles identified, screened, eligible for, and included in the systematic review. Figure format from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement," by D. Moher, A. Liberati, J. Tetzlaff, and D. G. Altman; The PRISMA Group, 2009, PLoS Medicine, 6(6), e1000097.

physical environments for greater function and independence, these devices must also accommodate deformities, provide postural support, and promote adequate pressure distribution over time.

An important consideration of the HAAT model is that assistive technology should not be an end in itself, but a tool for addressing the individual's functional needs. The process should be person-centered, not assistive technology-centered (Cook & Polgar, 2015b). When viewed through the HAAT model 'lens', the practitioner should assess support surfaces and determine what devices or technology are needed for PI prevention and increased function, while considering the human, context and activity demands. Thus, an effective seating system is not simply the one with the absolute highest level of pressure reduction through immersion, heat dissipation, moisture wicking, and friction reduction. An effective cushion must be reliable, low maintenance, low-weight, and cost-effective as well (Stephens & Bartley, 2018). While this narrative review focuses on the pressure relieving qualities of the cushions, the prescribing clinician must match the unique characteristics of each cushion material and design to the individual's needs and context in order to make an effective recommendation (Christensen et al., 2014).

3.5. Results

Seventeen peer-reviewed articles met the inclusionary criteria. Of the 17 included studies, two consisted of randomized control trials (RCTs) and 12 consisted of level IV evidence (cohort - within subjects) in which study participants trialed more than one style of cushion. These studies incorporated pressure mapping, magnetic resonance imaging (MRI), finite element (FE) modelling, or a combination of these measures. Only three studies assessed pressure occurrence,

one of which was purely observational. The results are presented by category of cushion design/materials, along with the general characteristics of these various systems in Table 3.1.

Table 3.1.

Evidence Table: Studies Included in Quantitative and Qualitative Synthesis

Lead author (pub. date)	n	Participants	Main Observations	Cushions included	Outcome measures	Level of Evidence*
Akins (2011)	0	Instrumentation only	Gel cushions resulted in the least amount of interface shear stress followed by air cell, elastic/VE foam, and honeycomb.	21 large market share cushions (non custom only)	Interface shear stress; interface pressure; horizontal stiffness	VI Descriptive
Arias (2014)	6	Able-bodied/ healthy	Air cushion with alternating pressure cells demonstrated lowest pressures	Alternating air cell; static air cell; foam	Pressure mapping	IV Cohort/ within subjects
Brienza (2018)	191	Nursing home residents aged 60+ at risk for PI	17.8% acquired PI, no difference between groups. Only pelvic rotation and w/c skills test (WST) were significant factors in PI.	ROHO Vicair	PI occurrence	II RCT
Brienza (2017)	6	SCI	No cushion proved more consistent in reducing pressure among the participants. Participants with less tissue thickness presented with higher IT pressures.	air-cell; contoured foam base and fluid pelvic insert; molded foam base beneath a fluid layer; plastic honeycomb structured material; foam and air combination; independent air cells contained within several compartments	MRI – tissue thickness; Pressure mapping	IV Cohort/within subjects
Brienza (2010)	222	65 and older at-risk nursing home residents	Eight (6.7%) participants in the SFC group and one (0.9%) in the SPC group developed IT ulcers (P=.04). Statistical significance was demonstrated for IT PI, and near statistical significance for IT and sacral PI combined. PI were higher among foam segment.	Segmented foam; skin protection cushion (air, gel, or foam)	PI occurrence	II RCT

Lead author (pub. date)	n	Participants	Main Observations	Cushions included	Outcome measures	Level of Evidence*
Call (2017)	11	SCI (n=10); Able bodied (control: n=1)	Off-loading cushion demonstrated decreased tissue deformation and interface pressure.	Off-loading; air-cell; unloaded	MRI; Pressure mapping	IV Cohort/within subjects
Crane (2016)	10	SCI	PPI values were lowest in the offloading (39±18mmHg), and highest in the air-cell (97±30mmHg)	Off-loading; off-loading with inserts; Single air cell-4in	Pressure mapping	IV Cohort/within subjects
Gil-Agudo (2009)	48	SCI	The dual compartment air cushion performed best in all areas of pressure measurement followed by gel, and the single chamber cushions performing similarly	low-profile air; high-profile air; dual-compartment air; and gel and firm foam	Pressure mapping	IV Cohort/within subjects
Levy (2013)	1	SCI	Simulation modeling analysis suggests air-cell cushions provide the most immersion and produce the least stresses.	Air-cell; gel; honeycomb	Finite Element modeling	VI Single descriptive
Meaume (2017)	152	SCI	Over the study period of 35 days 2 patients using a single compartment air-cell cushion (n = 78) developed PI, compared to 3 of those using a multiple compartment air cushion (n = 74).	Single compartment air cushion vs, multiple compartment air cushion	PI occurrence	VI Descriptive
Mendes (2019)	10	Paraplegia (n=5) Tetraplegia (n=5)	Overall, the Roho demonstrated the lowest PPI (111.7 ± 28.5) among the paraplegics. Tetraplegics had best outcomes in own cushions	Roho Quadro; Vicair; Jay with air insert; Participant's own cushion	Pressure mapping	IV Cohort/within subjects
Peko Cohen (2017)	1	SCI	Simulation modeling analysis suggests air-cell cushions provide the most immersion and produce the least stress.	Foam; air-cell cushion; off-loading	Finite Element modeling	VI Single descriptive
Sonenblum (2018)	4	SCI	The off-loading cushion appears to provide the lowest pressure. Not statistically analyzed pilot study.	Off-loading; Roho; foam	MRI – tissue deformation; Pressure mapping	IV Pilot study - Cohort/within subjects

Lead author (pub. date)	<i>n</i>	Participants	Main Observations	Cushions included	Outcome measures	Level of Evidence*
Sonenblum (2015)	17	SCI	Roho and gel had the lowest peak pressures	Roho; J2 gel; contoured foam	Pressure mapping	IV Cohort/within-subjects
Stockton (2007)	5	SCI	No pressure interface consistency outcomes among cushion. Users preferred cushions that were firmer and with higher pressures, suggesting users need more postural support which is not provided by best pressure relieving cushions.	Air in foam; Viscoelastic foam on high density foam; water-based gel and foam; viscoelastic gel and foam	Pressure mapping; qualitative	IV Cohort/within subjects
Tasker (2014)	30	Able-bodied	Custom-contoured cushions demonstrated the lowest interface pressures.	Flat baseline foam; contoured foam; custom-contoured foam	Pressure mapping	IV Cohort/within subjects
Trewartha (2011)	3	SCI	Roho air celled demonstrated decreased interface pressure.	Roho air-cell; Vicair 5 compartments with sealed cells	Pressure mapping	IV Cohort/within subjects

Note. Based on the following level of evidence scheme: Ackley, B. J., Swan, B. A., Ladwig, G., & Tucker, S. (2008).

3.5.1. Seat Cushion Design and Materials

Air cell. Air cell (sometimes called air-filled) cushions are made up of rubber bladder-like cells partially filled with air to support the user. These cushions are available in varying thicknesses and with either a single cell/compartment, or multiple cells for more control over areas of higher and lower pressure. Preferably, the cushion is inflated with just enough pressure to allow for envelopment and just enough flotation to prevent bottoming out. The advantages of air-filled cushions are the lightweight and long-wearing nature of the rubber material. However, they have inherent disadvantages that render them undesirable options for many users. The level of inflation must be carefully monitored as a rupture of the membrane or under-inflation will

lead to bottoming-out and PI risk. Over-inflation may result in an unstable surface which may lead to postural instability and impaired function. Thus, the user must be able to determine and maintain appropriate inflation levels to promote stability and pressure relief. The unstable nature of these cushions may also impair transfers to and from this type of surface (Stephens & Bartley, 2018).

A study by Brienza et al. (2018) consisted of 191 nursing home residents age 60+ and at-risk for PIs. Participants in this study were provided either a single compartment air-cell cushion (Roho), or a multiple compartment air cushion made up of many pyramid-shaped air-cell packets. Roughly 18% of residents acquired a PI during the study, with no statistical difference between cushions ($p = .77$). However, study results suggest wheelchair skills, as measured by Wheelchair Skills Test ($p = .004$), and the presence of pelvic rotation ($p = .02$), were significant predictors in pressure outcomes. Incontinence, had a relatively high odds ratio ($OR = 2.4$), but fell just short of statistical significance ($p = .07$).

An observational study conducted by Meaume et al. (2017) consisted of 152 SCI patients using either a single or multiple compartment air-cell cushion. Two out of 78 participants using a single compartment, and three out of the 74 using a multiple compartment air-celled cushions developed PIs over a period of 35 days. While no statistical difference was found between the two groups, results suggest air-cell cushions are effective at preventing PI occurrence.

Viscoelastic fluid. Also known as gel, viscoelastic fluid-based cushions are typically available as an overlaying pad or hybrid combination with other materials, providing varying degrees of gel viscosity. The overlay system consists of a gel pad placed over a firm base which is contoured with a deep well to help keep the gel pad in place and provide protection to the ischial tuberosities (ITs) and sacrum. While this system provides good pressure relief, a cooling

thermal property, a stable base, and according to one study, superior reduction in interface shear stress (Akins et al, 2011), it does present with some disadvantages. The loose-fitting structure of the overlay bag can result in dispersion of the gel and bottoming out, especially if not properly sized to fit the user. To prevent bottoming-out, the user or caregiver must frequently reset the gel by kneading the fluid back to the center of the pad. Furthermore, in cold temperatures, the gel can freeze, severely reducing its pressure-relieving performance (Stephens & Bartley, 2018).

Foam. Two types of foam materials are commonly used for cushions: polyurethane and viscoelastic. Polyurethane is most commonly used in seat backs and standard seat cushions as this material is inexpensive and lightweight. It is also commonly used as a base for pressure relieving cushions in combination with other materials. Polyurethane foam provides users with a stable and supportive surface but often requires increased thickness to prevent ‘bottoming out’. This is a naturally low-density foam that collapses with ease and yet has a ‘springy’ characteristic, which means it continuously ‘pushes back’ at the force being placed upon it. Thus, it is a poor choice of material for people with PI risk, as it does not envelop and redistribute the pressure (Stephens & Bartley, 2018). Other downsides to this material include moisture absorption, heat retention, and short-wearing lifespan, which are all contributors to PI risk (Hui et al., 2018).

Viscoelastic foam possesses many of the beneficial properties of polyurethane, but without the undesirable characteristics. While more expensive, viscoelastic foam is easy to shape and provides the user with a firm supportive surface. Commonly known as ‘memory’ foam, viscoelastic foam lacks the springy quality of polyurethane foam, which means that it holds its position when deformed. This gives it a much better pressure relieving characteristic as it complies to pressure and ultimately redistributes the user’s weight more evenly throughout the

surface. It also dissipates heat away from the body and is longer lasting and longer wearing than polyurethane (Stephens & Bartley, 2018). For these reasons viscoelastic foam is commonly used in custom-contoured seating solutions (Apatsidis et al., 2002).

Brienza and colleagues (2010) conducted a randomized control trial (RCT) in which 222 nursing home residents were randomly assigned either a segmented (flat) foam cushion (as is typically provided to this population), or a skin protection cushion (consisting of air, gel, or contoured foam). Eight participants using the segmented foam cushion developed PIs under the ITs, compared to one participant in the group using a skin protection cushion, suggesting a statistically significant difference ($p = .04$). The outcomes for PIs under the ITs and sacrum *combined* were less stark, suggesting non-significant difference ($p = .14$). The segmented foam was associated with 21 combined PIs, whereas the skin protection cushion was associated with 12. The authors did not describe the specific design of the cushions in the skin protection group, other than describing them as consisting of air, gel/viscoelastic fluid, contoured foam or any combination of these. A cushion consisting of more than one of these materials is referred to as hybrid.

Hybrid. These cushions commonly consist of a viscoelastic foam base with a gel or air insert. Many off-the-shelf pressure relieving cushions on the market today are hybrid cushions, and all are intended to combine the pressure-relieving characteristics of a very soft viscoelastic foam, air-filled, or gel cushion with the stability of a firm foam base, in order to provide optimal pressure relief, comfort, and support. Determining the effectiveness of hybrid cushions in PI prevention is made challenging by the virtue of the many variations of material combinations. This variety affords “mix-and-match” options to meet the unique needs of the client (Stephens & Bartley, 2018).

Off-loading custom-contour. Custom contoured cushions are an alternative to off-the-shelf cushions as they provide a custom fit to accommodate orthopedic deformities and greater levels of postural support (Stephens & Bartley, 2018; Stinson et al., 2013). These commercially available systems can be broken down into two categories: *standard* and *off-loading*. These cushions are formed to fit the specific shape of the wheelchair user through a process in which the shape of the buttocks, thighs, and/or back are captured and rendered into a custom-contoured cushion (Petito & Young, 2011).

This shape capture process can occur by using molding bags on which the client is positioned in a soft bead-filled bag leaving an impression which is then captured digitally through a three dimensional scanner (Petito & Young, 2011). Another method of creating custom seating is through a foam-in-place process, in which a liquid compound is poured into plastic bags fitted directly under the user while seated in a wheelchair. Once exposed to air, this compound transforms into foam, resulting in an instantaneous cushion that has expanded to match the shape of the user's buttocks, providing a direct fit (Lemaire et al., 1996). A third method uses the PinDot seating simulator consisting of sliding pins which conform to the user's shape. This renders a file which is manufactured into a cushion, similar to the molding bag method (Cook & Polgar, 2015c; PinDot, 2012).

An off-loading custom-cushion is contoured in a similar fashion to a standard custom-contoured system, as both are created from a loaded imprint upon a molding bag (Call et al., 2017; Crane, et al. 2016). The difference however, is that off-loading cushions are manipulated post shape-capture to provide an extra level of surface relief to identified problematic pressure areas, thus creating a highly modified version of the mold that no longer accurately represents the subject's body contours. The result is a cushion with a deep well carved in the center that

allows the ITs and coccyx to be suspended between the hips (Ride Designs, n.d.). The only two studies to include off-loading cushions in the present review suggest this design provides superior pressure relief compared to air-cell cushions (Call et al., 2017; Crane et al., 2016). The potential for researcher bias and small sample size however, limit the generalizability of these results.

Standard custom-contour. The shape-capture technique used for standard and off-loading style custom-contoured cushions is practically identical, however, unlike off-loading custom-contoured cushions, standard custom cushions are not highly recessed under bony prominences. Standard custom-contoured cushions are shaped to match the user as accurately as possible in order to provide a firm and stable support surface, while simultaneously providing an even pressure distribution across the contact surface area. Typically, these cushions are also made of viscoelastic foam which, as discussed previously, provide good tissue envelopment, pressure relief when contoured, postural support, thermal properties, and low weight (Petito, 2011).

A level IV study by Tasker and colleagues (2014) consisting of 30 participants, demonstrated significantly lower peak interface pressures for off-the-shelf style contoured cushions when compared to flat baseline, and even lower peak pressure values for custom-contoured systems ($p < .05$). These cushions consisted of identical viscoelastic foam material, thus highlighting the design and contour as the construct of investigation. Participants also found the custom-contoured cushion to be the most comfortable ($p < .001$) when compared to baseline (Tasker et al., 2014).

3.5.2. Pressure Prediction Technologies

Choosing a support surface for any client requires clinicians to possess experience, clinical reasoning skills, and the ability to conduct a client-centered evaluation that looks at the person's physical status, their abilities, activities and interests, and their lived environment in order to make informed decisions (Freundlich et al., 2017). The goals of prescribing wheelchair cushions for individuals at risk of PI are to choose a cushion believed to provide optimal pressure relief, which consists of a material that prevents retention of heat and moisture, and reduces shear, friction, and tissue deformity (Sonenblum et al., 2016). Measuring pressure relief is a challenge made more complex by emerging technologies such as finite element (FE) modeling (Al-Dirini et al., 2016; Peko Cohen & Gefen, 2017) and magnetic resonance imaging (MRI) (Moerman et al., 2017; Sonenblum et al., 2015). While early studies on PIs and seating cushions relied mainly on pressure mapping devices (Bush et al., 2015; Gunningberg et al., 2017; Kirkland-Walsh et al., 2015; Swain & Bader, 2002; Tung et al., 2015; Yuen & Garrett, 2001), current researchers now have a greater choice of outcome measurement tools (Sonenblum et al., 2015).

MRI and FE technologies used for pressure mapping are expensive, time consuming and typically limited to well-funded medical or engineering based-institutions. Furthermore, these technologies are often only used in very small or single-sample studies with the intent of theory development (Al-Dirini et al., 2016; Lee et al., 2017; Levy et al., 2014; Moerman et al., 2017; Peko et al., 2017; Sonenblum et al., 2015; Xiao et al., 2014). Pressure mapping is low-cost, readily applied in the clinic with larger populations, and can assist in ruling out cushions that provide unacceptably high-pressure areas (Sprigle & Sonenblum, 2011).

From the available research, however, it is not clear which of these systems provides the best PI risk detection. A systematic review conducted by Reenalda et al. (2009) suggests that a

relationship exists between interface pressure mapping and prediction of PIs, but cautioned that the included studies were limited by validity concerns, inconsistent outcome measures, and small sample sizes. However, upon further analysis of this review it appears that it was the older studies and those using primitive pressure mapping systems that did not demonstrate effectiveness, while studies consisting of newer tools were more successful. Specifically, all but one study that presented evidence of predictability used multi-sensor pressure mapping systems (Brienza et al., 2001; Conine et al., 1994; Drummond et al., 1985; Rosenthal et al., 2003); whereas those that did not demonstrate predictive ability used single-cell pressure pads (Economides et al., 1995; Sideranko et al., 1992; Tymec et al., 1997). These newer studies also included large sample sizes (418 total participants), while the sample sizes of the older studies totaled 121 participants. Pressure mapping has evolved from single sensor systems to the now common 1000+ sensor systems which provide a much more detailed ‘picture’ of pressure across the seating surface, and continue to be commonly used clinically and in research.

3.5.3. Pressure Relieving Characteristics

Optimal seat cushions are characterized as providing increased envelopment/immersion, contoured to shape of user, decreased heat retention, reduced friction and shear, and enough density to promote envelopment yet provide postural support (Stephens & Bartley, 2018). Immersion of the buttocks into the cushion is a primary method for protecting skin against PI. Deformation around the bony prominences such as the ITs and sacrum leads to shear of internal tissue which leads to breakdown of the cardiovascular system resulting in PI. The process for preventing deformation occurs by distributing the weight throughout the surface, which can be achieved by several means (Sonnenblum et al., 2018):

1. *Envelopment* or *seat compliance* refers to the ability of the cushion to deform to the shape of the user with the goal of reducing deformation of the buttocks. This concept is achieved through the use of materials soft enough to allow deformation of the cushion and retention of the tissue around bony prominences such as the ITs and sacrum (Sonenblum et al., 2018).
2. *Offloading* is aimed at reducing deformation of the tissues around the ITs and sacrum through a process of dispersal, in which the shape of the cushion transfers weight from bony prominences and onto structures more capable of withstanding greater loads for longer periods of time (Call et al., 2017). This design requires the use of firm materials and thus contradicts the concept of compliance or envelopment.
3. Custom-contour combines the concepts of *envelopment* and *offloading*, by providing increased contour which provides the benefit of envelopment, but typically with firm materials for greater postural support. The key to this design is the accuracy of the contour in matching the shape of the user's buttocks to reduce tissue deformity (Tasker et al., 2014).

Cushion thickness and density, particularly in non-contoured foam cushions, plays a significant role in pressure reduction. Hui et al. (2018) studied the effects of foam density and thickness on reducing pressure among participants of varying body-mass index (BMI). They found that a higher density foam cushion provides more postural support through the increased mass or compactness of the material itself, but may not allow for enough immersion or compliance to provide maximal pressure relief. Low density foam, however, offers improved pressure relief, but must be thicker in order to prevent 'bottoming-out'. Results suggest a low-density foam of at least 1.5 inches in thickness can provide a high level of pressure relief

regardless of subject BMI. While common belief is that the thicker the cushion, the better the pressure relief, Ragen et al. (2002), found that pressure relief could not be further reduced with cushion thickness greater than 3 inches. They suggest that low foam density and thickness between 1.5-3 inches provide optimal pressure relief among flat non-contour cushions (Hui et al., 2018; Ragen et al., 2002). However, these results do not necessarily apply when contour or off-loading design principles are added to the design of the cushion, as these typically incorporate higher density foams in order to better preserve the contour design (Apatsidis et al., 2002; Call et al., 2017; Crane et al., 2016).

3.6. Discussion

The aim of this review is to provide evidence-based recommendations for clinical application, and potentially highlight areas of need for further research. The hope is to provide clinicians and consumers with a better understanding of the evidence among a myriad of literature rich in efficacy, but often lacking external validity outside of highly controlled research settings. Sprigle and Sonenblum (2011) declare “*for the most part* there is no single seat surface that is optimal for all users”. This statement suggests that effective pressure relieving cushions may have unifying characteristics, however prescription should always consider the unique needs of the individual.

The greatest insight from the present review are those gleaned from the three studies that use PI occurrence as an outcome measure (Brienza et al., 2018; Brienza et al., 2010; Meaume et al., 2017). They suggest that air cushions appear to offer the best pressure relief, but are not entirely preventative. The substantial presence of PIs among these studies, regardless of cushion, highlights the role the extrinsic and intrinsic risk factors described earlier play on PI occurrence.

Overall, air-cell cushions appear in 16 out of the 17 studies included in the present review, and were described as providing optimal pressure relief in eight of these. This includes results in which the air-cell cushion was the single variable, as well as in studies in which the air-cell, viscous fluid, and contoured foam were grouped together as a conglomerate variable in comparison against flat baseline foam.

The only cushion that may outperform the air-cell design is the off-loading custom-contoured cushion, which is shaped to the participant and then further reshaped to off-load weight bearing pressure away from the ITs and sacrum. In the off-loading cushion design, weight is redistributed onto the femurs and tissue surrounding the buttocks which are better able to withstand interface pressures due to the lack of bony prominences in these areas. This cushion design was studied in two cohort within-subjects design studies (level IV). Call et al. (2017) and Crane, et al. (2016) found that this design has the least impact on IT pressure and tissue deformation when compared to air-celled cushions, according to pressure mapping and MRI scanning. These results are not surprising as the weight of the ITs and sacrum are mostly, or fully, off-loaded and dispersed to other areas better able to support the user's weight.

The standard custom-molded cushion studied by Tasker et al. (2014) also demonstrated improved performance over a contoured (non-customized) and baseline cushion, with improved pain reduction as well. This cushion is designed to provide a posturally supportive surface incorporating firm viscoelastic foam, often as a seat and backrest combination seating device (Petito, 2011). Similar to the off-loading cushion, it is not clear how this design performs in regards to minimizing shear, nor is it known how it compares to actual off-the-shelf pressure relieving cushions, but with the intention of maximizing contour and contact, this design might be more 'palatable' for users wary of the off-loading cushion design.

3.6.1. Implications for Research

Results from the present review suggests two seating characteristics appear to play a crucial role in PI prevention: immersion and contour. This is validated by the two types of cushion designs that most commonly appear to provide optimal pressure relief. Air-celled cushions provide the highest level of immersion which translates to increased contact area. This allows for a high degree of pressure relief from an off-the-shelf seating device that is fairly low cost and does not require a lengthy shape-capture and manufacturing custom build process. Custom-contoured (traditional and off-loading) cushions provide pressure relief through the process of substantial amounts of contour. This process however, involves added time, labor and effort in the shape-capture and manufacturing process, which ultimately leads to greater cost.

Air-celled and custom-contoured cushions provide high levels of PI relief, but differ in terms of surface stability. The impact of cushion stability on patient's perceived comfort and postural support are seldom reported in the literature and worthy of further investigation, as the impact a cushion plays on function should be just as much a priority as its ability to reduce risk of PIs. Future research should consist of studies comparing the PI risk, patient satisfaction, postural support, and impact on function of air-celled and custom-contoured cushions.

Current literature rarely assumes a constructivist perspective in identifying the interactional impact of cushion materials/design, pressure management techniques, and shear as a whole against PI prevention. This is an area worthy of further investigation as research needs to move further away from clinically controlled simulations and toward a greater emphasis on effectiveness, incidence and holistic understanding of PI mitigation. Hence, research using proxy outcome measures such as MRI, FE modelling, and pressure mapping are limited in generalizability and should incorporate PI occurrence as outcome measures whenever possible.

Reducing shear appears to play an important role in pressure management. Air-cell and viscous fluid (gel) cushions appear to provide significantly decreased levels of shear (Akins et al. 2011), but this characteristic has been seldom studied and deserves greater focus, as this can have significant clinical implications specifically as it relates to transfers, recline, and mobility (Zemp et al., 2019). Wheelchair use inevitably means that the user will participate in mobility in their environment, as well as perform transfers into and out of the seat. Using pressure mapping as a proxy for pressure relief only captures this construct in an isolated and clinically controlled environment in which participants sit statically in a cushion wired to a computer in order to allow for data recording and gathering. Not only should greater variations in these measures be expected in a real-world environment in which the user performs activities of daily living, but the shear forces experienced as the user travels over changing floor surfaces, ramps, surface imperfections, vibrations, etc. can play a significant role in impact on tissue health.

Thus, shear may have substantial impacts on PI, and deserves further investigative attention across research of various cushion designs. Furthermore, pressure relief management practices such as power seat tilt/recline, or forward/lateral weight shift positioning changes are a main factor in pressure management for at-risk populations (Zemp et al. 2019). Weight shifting, and tilt/recline positioning changes are commonly prescribed as a method of PI prevention, however, the literature consistently suggest these activities are rarely adhered to as prescribed, or are not executed accurately enough to have a positive effect (Latimer et al., 2014; Sleight et al., 2019; Zemp et al. 2019). Hence, future research should consider the impact of cushion design (air-celled vs. contour) on shear forces, in the context of tilt and space seating, as this is a likely seating configuration for individuals with severe mobility impairments.

3.6.2. Limitations

Results of these studies are challenging to compare and reduce to singular conclusions. Few studies use actual PI occurrence as an outcome measure, while most depend on proxy measures such as pressure mapping, MRI or FE modelling, as well as tissue oxygen perfusion.

Statistical comparison between studies which share similar outcome measures, such as pressure mapping, is extremely limited due to the differences in pressure mapping technologies, and research methodologies of data gathering, and reporting methods. Pressure mapping systems commonly consist of 256 (16x16) or 1,024 (32x32) sensor grids. Even when similar sensor grids are used, the outcome measures can be significantly varied between studies, with one article reporting “peak pressure” as the number of sensors reaching 100 mmHg, while another reports the peak pressure index (a number obtained by locating the cell with the highest reading, and averaging it with the readings of the 8 sensors surrounding it). Data gathering methods can also vary significantly, such as the time allowed for the participant to ‘settle’ into the cushion before data gathering, as well as positions, such as varying differences in tilt and recline.

Undoubtedly, PI occurrence is the optimal outcome measure to determine the effectiveness of pressure relieving cushions, but conducting these types of large-scale studies is increasingly challenging and may pose ethical dilemmas if at-risk populations are provided cushions commonly regarded as inferior.

3.7. Conclusion

The present narrative review aimed at gathering evidence on optimal pressure relieving seat cushion characteristics for reducing PI risk. Several seat cushion materials and designs are commonly available and prescribed for wheelchair use, however, the literature is inconsistent in suggesting any off-the-shelf cushion as superior in terms of providing optimal pressure relief.

Different cushion designs and materials address the PI prevention methods differently. These include: (a) immersion and tissue envelopment (air-cell, viscous fluid), (b) firm off-loading surface with recessed wells under the ITs/sacrum (off-loading), and (c) significant buttock matching contour in order to increase surface area and pressure distribution (contoured and custom-contoured foam). The few studies that actually include PI occurrence as an outcome measure point to air-celled cushions as the optimal design for pressure relief. Other designs such as off-loading and custom-contoured have yet to be tested in PI occurrence studies, thus little inference can be made regarding their pressure relieving capacity until more rigorous research is conducted.

A consistent finding observed across these studies is the significance of immersion and contour on reducing pressure interface, as any cushion consisting of these characteristics consistently outperforms baseline foam cushions. This finding is further emphasized by the emerging, yet under-researched, perspective that shear plays a significant role in PI development, particularly when a wheelchair is used in context. Overall, air-cell cushions appear to provide superior immersion and shear reduction. However, for those with greater postural needs or orthopedic deformities, standard or off-loading custom-contoured cushions appear to provide a high level of pressure relief, although further research is needed.

While the seat cushion is a central factor in pressure management, it is rarely the single PI outcome predictor. Many factors influence PI risk, including support surfaces, positioning, internal/external patient factors, activities, and environmental supports. PI management must consist of a holistic approach in which clinical decisions are made based on these factors.

3.8. References

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4. Research Paper Three. Unloaded Custom-Contoured Seating: A Pilot Study

4.1 Introduction

This paper reports on a single-subject pilot study which compared the pressure relieving capacity of a custom-contoured wheelchair seat cushion fashioned using an innovative shape-capture method to the pressure relieving capacity of off-the-shelf wheelchair seat cushions. This paper includes a description of present loaded shape-capture methods, and a rationale for an innovation in this process referred to as *unloaded shape-capture*. This paper will discuss the purported advantages of the unloaded shape-capture method over the traditional method, and report objective data and analysis on the outcome measures of interface pressure, contact area, comfort, and weight. The paper concludes with findings from the pilot study.

4.2 Literature Review

Individuals with upper motor neuron lesions (UMNLs) often present with trunk and pelvic deformities, impaired posture control, and abnormal muscle tone requiring custom wheelchair seating solutions (Freundlich et al., 2017). While some of these positioning challenges can be corrected with the use of planar seating, some cannot. Christensen et al. (2014) describe the importance of the clinician's role in assessing what deformities can be corrected, and what must be accommodated. Furthermore, individuals with severe mobility impairments are at risk for developing pressure injuries (PIs) due to prolonged static positions particularly in wheelchair seating, where a significant portion of the individual's weight is transferred directly onto the ischial tuberosities (ITs) for extended periods of time (Freundlich et al., 2017). Thus, in addition to addressing postural and orthopedic deformities, seating systems for this population must also provide pressure relief (Christensen et al., 2014; Freundlich et al., 2017).

Many off-the-shelf cushions are designed to provide pressure relief, but limited options exist for individuals with postural issues or orthopedic deformities (Stephens & Bartley, 2018; Stinson et al., 2013). Custom-contoured seating systems are viable and commonly prescribed alternatives to off-the-shelf cushions. These cushions are formed to fit the specific shape of the wheelchair user through a process of ‘modeling’ the buttocks, thighs, and sometimes back with the use of molding bags. The imprinted shape is then captured digitally and used to create a custom-contoured foam (viscoelastic) cushion intended to provide the user with an optimal combination of pressure relief and postural support (Petito & Young, 2011). This made-to-fit system: (a) accommodates deformities, (b) provides postural support when paired with a supportive backrest, and (c) aides in PI prevention by reducing tissue deformation under load (Petito & Young, 2011). It is this deformation that causes the internal tissue shear that leads to PI over time (Sonenblum et al., 2018). While various shape-capture methods are used in present clinical practice, all occur under loaded conditions (Lemaire et al., 1996; Petito & Young, 2011). This study tests the hypothesis that an unloaded shape-capture method may provide improved accuracy, resulting in reduced seating interface pressures and PI risk.

4.2.1 General pressure relief principles

Despite inconclusive evidence for ‘best’ pressure relieving cushions, one research outcome appears consistent: Cushions which provide significant levels of immersion or contour are significantly better at reducing tissue deformity and interface pressure than others. In a randomized clinical trial of 180 long-term care facility residents, Brienza et al. (2010) found that those prescribed with a commercial off-the-shelf pressure relieving cushion had fewer episodes of PI than those prescribed a plain four-inch thick cross-cut (non-contoured) foam cushion. After six months, 29 (32%) participants presented with IT and/or sacral ulcers in the control group,

compared to 13 (15%) in the intervention group. In a trial of 30 healthy individuals, Tasker et al. (2014), compared flat foam, off-the-shelf style contoured, and custom-contoured cushions shaped from a molded shape-capture method. These cushions were all made from foam of the same density. Pressure mapping revealed significantly lower peak interface pressures for the off-the-shelf style contoured cushion and even better performance for the custom-contoured system. Participants found the custom-contoured cushion to be the most comfortable as well (Tasker et al., 2014).

4.2.2 Traditional contour shape-capture methods

A description of the most common presently practiced methods for creating custom-fitted support surfaces is provided here as a means to provide background and context. This description is informed by research literature (Petito, 2011; Stephens & Bartley, 2018) and this researcher's 20 years of experience as an occupational therapist specializing in wheelchair seating.

The traditional method of fitting a custom-made wheelchair seating system proceeds as follows:

1. Patient is assessed for the need of a wheelchair seating system that provides both postural support and pressure relief. The patient is often referred to a seating clinic by a physician (most commonly a physiatrist), however, the recommendation for the type of seating system, such as a custom-contoured cushion, is usually informed by the therapist (Physical Therapist or Occupational Therapist) specializing in wheelchair seating.
2. The therapist performs a mat evaluation in which the patient is assessed biomechanically for joint range of motion and postural deformities, and the wheelchair is evaluated for hardware required to mount a new cushion. This evaluation should also consider a holistic assessment of the individual's health, diagnosis, skin condition, present seating system, sitting balance, and sensation (Minkel, 2018), and can incorporate screening tools

such as the Braden scale (Iranmanesh et al., 2012) and outcome measures for pressure prevention such as pressure mapping (Stinson et al., 2017).

3. The patient is seated onto malleable bead-filled molding bags (one for the seat and one for the back). The patient and therapist work to achieve an optimal positioning placement that appears to provide comfort, support and pressure relief, while on the malleable bags. Once this balance is achieved, air is immediately vacuumed from the bags via an extraction pump. This process hardens the bags leaving a solidified impression of the patient's physical contours on the molding bags. At this point the patient is carefully transferred off of the molding bags to prevent distortion of the imprint.
4. The equipment provider (vendor) translates the imprint made on the molding bags into a digital file that is then sent to the manufacturer and made into a seat cushion. Once the imprint has been successfully captured, the patient is scheduled to return to try out the new cushion.
5. Translating the imprint into a digital file consists of scanning the imprint either through the use of a 3-dimensional (3D) digital scanner, or a digitizing pen rolled over the imprint within 1/2-inch increments in order to capture the contours of the surface.
6. The digital file is sent electronically to the manufacturer to process the file and prepare it for input into a computerized numerically controlled (CNC) router. Guided by the image contained in the digital file, the router cuts the exact imprint shape into a 4-inch viscoelastic foam block.
7. The newly custom manufactured seat cushion is then shipped to the equipment provider, and presented to the patient for an initial fitting. Once the equipment provider, therapist and patient are satisfied with the fitting, the cushion is sealed, covered, and fitted with

hardware in order to be attached to the patient's personal wheelchair. This molding bag method requires some technical skill, but is forgiving in the event of errors, as it allows for repeat molding until the fit is satisfactory, unlike foam-in-place methods.

4.2.3 Other shape capture methods

Foam-in-place and *PinDot* (PinDot, 2012) are both bead bag alternatives to cushion molding which are falling out of favor in the custom-contoured wheelchair seating industry, due to the inherent challenges, limitations, and difficulty of use. The foam-in-place method requires the mixing and pouring of liquid chemical compounds into a seat base within a plastic bag. When the compounds are mixed together and exposed to air, the liquid expands and converts to foam. This material conforms to the shape of the patient who is seated directly upon it mid-way through the expansion and rising process, resulting in the creation of a cushion fitted to the user. The foam is then trimmed of excess material, ensuring a proper final fit. This method has the benefit of allowing the cushion to be created on-site and can provide maximal contour, however, it requires a significant level of skill and preparation, and requires precise execution of the process (Lemaire et al., 1996). An error may result in discarding the cushion, and starting the process over.

The PinDot system requires the use of a seating simulator equipped with impression pins built into a purpose-built seat and backrest device (Cook & Polgar, 2015a; PinDot, 2012). The impression pins slide to accommodate and conform to the shape of the patient. When the desired fit and position appear to be achieved, the pins are locked into place, creating a mold of the patient's body contours. This impression is recorded onto a file which is used to convert a foam block into a custom-contoured cushion via a CNC router, similar to the molding bag method describe previously.

In general, the PinDot device requires less skill than the foam-in-place method, but is limited in the available depth and accuracy of the contour. This method is most appropriate for patients who do not require significant levels of contour but may present with orthopedic anomalies that require accommodation unavailable in off-the-shelf seating systems (Cook & Polgar, 2015a; PinDot, 2012). This system has also become decreasingly used in favor of the molding bag method which is more accurate and more accommodating of severe deformities (Invacare, 2012).

4.2.4 Innovations in contour shape-capture methods

In the past several years, a few novel shape capture methods have been proposed. Li et al. (2014) captured the cushion user's anatomical contours using a pressure mapping system, thus eliminating the need for a molded bag shape-capture effort. Through the use of a complex algorithm designed by the authors, a custom-contoured cushion was carved from a foam block. As expected, this custom-molded method provided better pressure relief than a non-contoured foam cushion. However, effect sizes were not provided, and no comparison was made to any other system beyond the non-contoured baseline cushion.

Rosenthal et al. (1996) compared an innovation in seat cushion technology named Total Contact Seat (TCS) (based on prosthesis design principles) to commonly used pressure relieving cushions. In a study of 47 wheelchair users, TCS provided improved pressure relief under the coccyx and ITs compared to three commercial pressure relieving cushions ($p < .001$). In a follow-up study of 47 participants, TCS proved significantly more effective at healing stage 3 and 4 PIs than an air mattress ($p < .0001$). A follow-up study (Rosenthal et al., 2003) found similar results comparing TCS to pressure relieving mattresses.

Interestingly, TCS is hardly a cushion at all. It is described merely as a plastic shell lined with a very thin layer of foam, and with recesses cut under the ITs, coccyx, and greater trochanters. The TCS's padding is minimal, as it is not intended to envelop the user, but rather is made to off-load the bony prominences by firmly supporting the surrounding tissues. While this seating technology appears promising, it is not a commercially available device, and it is not clear from these studies how this design impacts comfort and function. It is apparent from the TCS study results that a contoured shape is an important element of cushion design. Simply providing at-risk populations with soft surfaces appears to be less effective than providing a surface contoured to the specific shape of the user.

Off-loading cushions (OLC) are similar in design principles to the TCS and custom contour cushions. This is essentially a custom contoured cushion, in which bead-filled molding bags are used in the shape-capture process to create a custom fit, but with one essential difference: The foam material located under the ITs and sacrum is purposefully recessed with a greater portion of the load placed onto surrounding tissues and thighs. The OLC cushion has been shown to provide superior pressure relief when compared to air-cell cushions in small samples of individuals with SCI using magnetic resonance imaging (MRI) and pressure mapping instruments (Call et al., 2017; Crane et al., 2016; Sonenblum et al., 2018). However, Peko et al. (2017) found the opposite to be true using finite element (FE) modelling.

These opposing outcomes are a result of differing outcome measures. The studies claiming OLC cushions as superior, assess pressure outcomes on the physical deformation of tissue directly under the bony prominences, with the assumption that the off-loading onto femurs and other bony surfaces are more resistant to creating PI breakdown. Using FE modelling, however, Peko et al. (2017) suggest the overall tissue deformation throughout the buttocks is

lower on the air-cell cushion. These differences appear logical and efficacious, as the OLC reduces PI risk by deflecting weight bearing onto flatter bony surfaces, while the air-cell reduces interface pressure by significantly increasing immersion and compliance throughout the entire surface. While air-celled cushions appear to have some effectiveness in PI reduction as noted in randomized control trials in which outcomes included pressure occurrence (Brienza, et al, 2018; Brienza et, al. 2010, Maume, 2017), similar rigorous research of OLCs is lacking.

The OLC is commonly prescribed for individuals with lower level SCIs (Call et al., 2017; Crane et al., 2016; Sonenblum et al., 2018; Peko et al. 2017). This cushion design provides pressure relief for those with good upper extremity control (Call et al., 2017, Crane et al., 2016; Sonenblum et al., 2018), but may not accommodate postural deformities or severe muscle tone imbalances. The traditional custom-contoured cushion appears to be more appropriate for individuals with severe upper motor neuron lesion-related mobility impairment who require a custom cushion with greater postural support (Petito, 2011).

4.2.5 Synthesis of the Literature

All cushion molding methods share a *loaded* shape-capture procedure in common, in which the contours of the body are captured while seated (Petito, 2011; Tasker et al., 2014; Li et al., 2014; Apatsidis et al., 2002). Seating a patient on the molding bags allows gravity to act on the body, pushing the buttocks and thighs into the molding bags. This is effective for the purpose of making an impression upon the molding bags, however, the impression created is that of the buttocks and thighs compressed under the pressure of gravity. It is this deformation that the pressure relieving cushions should be preventing, as research suggests that deformation of the gluteus muscles, adipose, and soft tissues is directly related to the internal shear forces that cause PIs (Sonenblum et al., 2015).

Thus, the traditional loaded shape capture method may inaccurately reflect buttock and thigh contours, thus limiting the overall pressure relieving capacity of the seat cushion. If the shape of the buttocks and thighs is captured in an unloaded position without deformation, the result might be a more accurate fit, better weight distribution, improved comfort, and postural support. This study compares the two methods.

Clinicians have explored the use of direct three dimensional (3D) scanning of body contours such as heels, residual limbs, and hands in order to improve the fit of custom made orthotics and prosthetics with success (Crytzer et al., 2016; Telfer & Woodburn, 2010). This technology has been put to use in the design and manufacture of prosthetics and orthotics because it is cost effective and provides accurate shape capturing. Direct 3D scanning also saves time and costs associated with the manufacturer of wheelchair cushions due to the decreased need for large and cumbersome seating simulators/molding systems used in traditional shape-capture procedures (Lemaire et al., 1996; Petito, 2011; Yuen & Garrett, 2001). Research incorporating 3D scanning in unloaded shape capture methods for custom-contoured seating design, the focus of this study, has not been reported in the literature.

4.3 Purpose

This paper reports on a pilot trial designed to compare the pressure relieving capacity of a novel unloaded shape-capture method with that of non-contoured and off-the-shelf pressure relieving cushions. The study also gathered data on the subject's perception of postural support provided by each cushion. The study was conducted by this student researcher at the Graduate Occupational Therapy program, at Dominican College, NY, and presented as a poster at the New York State Occupational Therapy Association conference (Damiao, 2019).

The purpose of this study was to quantitatively measure the pressure relief, comfort, and postural support characteristics of an unloaded shape-capture method in comparison to off-the-shelf pressure relieving cushions, as described by the following research question and hypotheses:

- *Research Question: Does a cushion designed using the direct unloaded shape capture method provide improved pressure relief compared to off-the-shelf pressure relieving cushions?*
- *Hypothesis 1: A custom-contoured cushion created from an unloaded shape-capture method will result in decreased interface pressure, as measured by pressure mapping, when compared to off-the-shelf pressure relieving cushions.*
- *Hypothesis 2: A custom-contoured cushion created from an unloaded shape-capture method will result in improved perceived postural support when compared to off-the-shelf pressure relieving cushions.*

4.4 Theoretical Framework

The Human Activity Assistive Technology (HAAT) model (Cook & Polgar, 2015b) is applied by rehabilitation professionals in supporting individuals who may benefit from assistive technology in performing everyday tasks. Assessment using this model typically involves observing *activity/task* demands, followed by assessment of *human skills* and structures, which include neuromusculoskeletal, mental, and sensory functions, among others in *context*, and ultimately the application of an assistive technology to aid in participation. The focus of this paper is the trial of an innovation in the shape-capture method of custom-contoured seating. This type of seating is an assistive technology designed to provide a balance of postural support and pressure relief (Freundlich et al., 2017).

4.5 Methods

One able-bodied participant was recruited via a convenience sampling method among a cohort of graduate occupational therapy students. The participant was informed of the experimental procedures of the study and approval was obtained by the Dominican College, Orangeburg, NY, Institutional Review Board (IRB). The participant was selected in accordance with the following inclusion criteria:

- Height within one standard deviation of the national average for an adult female (mean = 65 inches; SD = 3.5 inches; range = 61.5 inches to 68.5 inches) (Census.gov, 2010).
- Weight within the one standard deviation of the national average for an adult female (mean = 168.5 lbs.; SD = 63.2 lbs.; range = 105.3 lbs. to 231.7 lbs.) (Census.gov, 2010).

The investigators of this study included an occupational therapy research instructor (present author) and four occupational therapy graduate students at Dominican College, in Orangeburg, NY. The present author is a licensed occupational therapist (OT) practicing in the New York/New Jersey area, experienced in custom seating, and at the time of the study was certified by the Rehabilitation & Engineering Society of North America (RESNA) as an Assistive Technology Professional (ATP), and Seating and Mobility Specialist (SMS). All pressure mapping measurements and data analysis were recorded by the present author with assistance from graduate occupational therapy students.

4.5.1 Data Collection Procedure

This study compared the pressure relieving capacity of five cushions, including two off-the-shelf cushions, standard wheelchair sling seating, a custom contoured unloaded shape-capture cushion (USCC), and a non-contoured foam (NCF) block (see Table 4.1). Both USCC and NCF cushions are made of the same viscoelastic foam, manufactured by SunMate®

(Dynamic Systems, Inc., n.d.) and rated as ‘firm.’ This is a standard material used in custom-contoured seating.

Table 4.1

Cushion model and size specifications

Cushion	Material	Dimensions
SunMate [®] unloaded custom-contoured foam block (USCC)	<i>Firm</i> viscoelastic polyurethane foam	17” W X 18” D X 4” H
SunMate [®] non-contoured cushion (NCF)	<i>Firm</i> viscoelastic polyurethane foam	17” W X 18” D X 4” H
Permobil Comfort M2	Dual density foam, molded foam base, and Quadra3D [®] Gel pack.	18” W X 18” D
Roho 3-inch air cell	Air filled cells	18.25” W X 18.25” D X 3.25” H
Standard wheelchair sling-seat	Standard fabric sling surface	18” W x 18” D

Note. Description of cushions included in comparison, including construction/materials, and dimensions (Width x Depth x Height)

Session 1. Procedures for this study occurred over two sessions. During the first session, goniometric measurements of the participant’s hip and knee flexion were taken in the seated position in a wheelchair with sling seating. In preparation for this shape-capture session, the participant was asked to wear tight-fitting clothing, to avoid ripples in clothing. The participant was positioned supine (facing the ceiling) on a mat, with hips and knees flexed to resemble the seated position. The EinScan Pro 3D handheld scanner (Shining 3D, 2016) was used to directly capture the contours of the participant’s buttocks and thighs, rendering the image as a 3D file. This file was then processed using the popular computer-aided design (CAD) software program: SketchUp. The file was transformed into a ‘negative’ image in order to change the convex

curvatures of the buttocks and thighs into concave. The file was then prepared and imported into the ShopBot PRSalpha 96-48-8 Computer Numerical Controlled router (CNC) (ShopBot, 2017), where the block foam was carved into the contoured cushion. Once this cushion was created, the participant was invited to return for the data gathering session (session 2).

Session 2. Measurements were obtained for all five seating systems. Goniometric measures assured the same hip and knee angles, and general posture on all seating surfaces to assure the variables were controlled for. The participant remained seated in each cushion for eight minutes prior to data recording, as this ensured stabilized pressure values. Data was gathered by the researcher with assistance from graduate OT students. The participant was then asked to rank the level of perceived postural support provided by each cushion, on a scale from 1 (least) to 5 (most).

4.5.2 Outcome measures

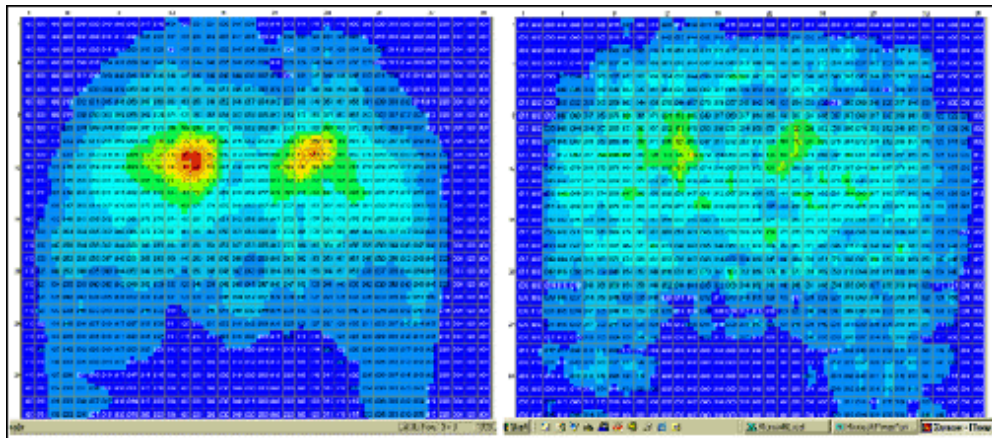
Descriptive data was collected and includes the *peak pressures index (PPI)*, *average pressure*, and *surface contact percentage*. The MeasureX mapping system by SensorEdge (MeasureX, 2018) was used to record interface pressure measurement. The peak interface pressure, represents the pressure experienced by skin tissue interfacing with a support surface. For example, a subject seated on a hard and flat surface, such as a wooden kitchen chair, will experience increased amounts of pressure under the ischial tuberosities. Sitting on this surface can cause discomfort after some time as the bony prominences create increased pressure over a small surface area, prompting the individual to weight shift or change positions periodically to relieve this pressure. A pressure mapping reading on this type of surface would identify higher peak interface pressures under the ischial tuberosities (ITs) and uneven pressure throughout the rest of the surface area, increasing the PI risk. The purpose of custom contoured foam seating is

to substantially reduce the peak pressure, allowing for longer duration of sitting before skin breakdown occurs.

Pressure mapping provides a visual graph of peak and overall pressure. Figure 4.3 demonstrates the same subject sitting on two different types of cushions. The color gradient, in which blue is low pressure and red is high, suggests this cushion provides inadequate pressure distribution. The cushion on the right appears to improve pressure distribution as there are no areas of red or orange. Improved pressure relief is achieved by increasing the pressure distribution throughout the surface area, typically by increasing surface area contact. As a result, the cushion on the right (low peak pressure) presents with less blue area (increased contact) as compared to the cushion on the left.

Figure 4.1.

Example comparison of pressure relief through pressure mapping



Note. Pressure mapping visual comparison. Cushion on left presents with high pressure points, while cushion on right presents with low pressure point, and improved pressure distribution (University of Washington, 2004).

The pressure sensor pad contains over 1024 sensors. Individual sensors are only accurate up to approximately 200 mmHg of pressure. The software program limits the readings for

individual sensors at 200 mmHg, which may not be the actual peak pressure experienced at the interface under the ischial tuberosities (ITs). For this reason, researchers in this field have commonly adapted the *peak pressure index (PPI)* which takes the most central point of pressure directly located under the IT, plus the immediately surrounding sensors for a total of nine sensor readings. The mean of the nine sensors is calculated to provide the PPI for that specific ‘hot spot’ (Chen et al., 2014; Crane et al., 2016; Sonenblum et al., 2018; Stinson et al., 2013). This helps to compensate for inaccuracy in pressure readings resulting from the saturation of individual sensors (> 200 mmHg).

A Wilcoxon signed-rank test was performed to calculate the mean difference in PPI between the USCC and the comparison cushions. This is the appropriate tool to compare group means when assumptions of sample size and normality are violated (Cronk, 2020). A Bonferroni correction is appropriate in this case, in order to minimize the risk of type I errors, thus $\alpha = .01$ is used as the determinant of statistical significance.

The *average pressure* value refers to the mean of all the sensor points. Similar to the PPI, a lower average pressure reading indicates improved pressure relief, overall. The *contact surface percentages* indicate how much of the subject’s body is in contact with the pressure map. A higher value for this number is preferable as it indicates ‘evenness’ in pressure distribution. These values are reported for all surfaces, and includes visual pressure mapping, which adds further context to the objective numerical data.

4.6 Results

4.6.1 Pressure Relief

The unloaded shape-capture cushion (USCC) demonstrated the lowest average pressure (36.5mm/Hg) and PPI (130 mm/Hg), but only marginally better than the next best performer: the

Permobil Comfort M2. The M2 demonstrated the most consistent pressure distribution across all four quadrants with the lowest standard deviation of 10.2 compared to the USCC at 15.3, which was only marginally better than the Roho (16.5). The Roho air-cell demonstrated the highest contact area (78.61%), while the Comfort M2 and USCC provided slightly less (76.17% and 73.93% respectively). The non-contoured foam (NCF) and standard sling seat demonstrated the worst performances for all outcome measures (see Table 4.2).

Table 4.2

Comparison of Pressure-Interface Measures

	Sling Seat	Non-Contour Foam	Permobil Comfort M2	Unloaded Shape-Capture Cushion	Roho
Average pressure (mmHg)	45	62	37.5	36.5	60
PPI (mmHg)	>200	>200	131.4	130.6	146.7
Quadrant Distribution (SD)	22	21.6	10.2	15.3	16.5
Contact area (%)	62.7	52.93	76.17	73.93	78.61

Note. Items in bold represent best performance for each measure. Sling seating and non-contoured foam demonstrated ceiling peak pressure index (PPI) values, assumed to be higher than the reported value of 200 mmHg.

A two-tailed non-parametric Wilcoxon signed-rank test was calculated to compare the mean difference in PPI between the USCC among the other cushions. Differences between the USCC and Comfort M2 ($z = .296$, $p = .767$), and Roho ($z = .280$, $p = .779$) were not significant. However, there was a significant difference between the PPI of the USCC and both sling seat

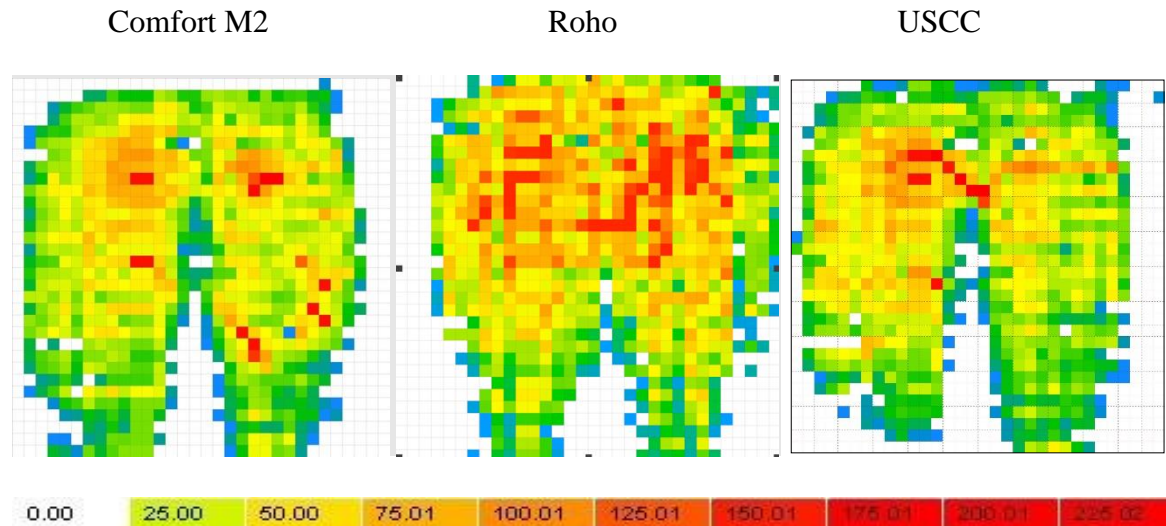
and baseline NCF cushion ($z = 2.673$, $p = .008$). Both the sling seat and baseline NCF had identical PPIs consisting of pressure areas in which all nine sensors peaked at 200 mmHg. This analysis was conducted by using the nine sensor cluster readings that make up the PPI for each cushion reported (see Appendix A).

One of the benefits of pressure mapping software is the visual pressure patterns with color gradients which provide clinical context to the ‘hot spots’ which could increase risk for PI. As shown in Figure 4.2, the Comfort M2 pressure map appears to show hot spots directly under the ITs. The Roho cushion map shows hot spots dispersed on the ITs, and with narrow dispersion through the thighs. The USCC map shows one hot spot under the right IT as well as a string of ‘peaked’ sensors in a diagonal line between the ITs. It is possible that this string of ‘peaked’ sensors more likely to be faulty readings resulting from a crease in the pressure pad. Any crease in the interface material may cause inaccurately high-pressure readings, which is a challenge to avoid in high contoured surfaces, such as with the USCC. This further validates the use of PPI as a measure of peak pressure versus individual sensor readings. Upon closer inspection of this string of peaked sensors, the immediately surrounding sensors read substantially lower, thus suggesting they are not an actual area of high pressure, unlike the area directly under the right IT in which multiple sensors are peaked and near peaked, thus verifying the ITs as an area of high pressure.

Irrespective of the subjective interpretation of visual maps, the objective data suggests the USCC appears to provide the best potential for pressure relief, followed by the Comfort M2, Roho, sling seating, and NCF by rank. Interestingly, the Roho provides the greatest contact area as this cushion is designed for maximal immersion; however, the cushions with greater contour (USCC and M2) provide lower peak and average pressures. They accomplish this despite the

Figure 4.2.

Pressure Patterns of the Permobil Comfort M2, Roho, and SunMate® USCC



Note: Visual representation of pressure sensor readings through a white (low pressure) to red (high pressure) color gradient.

stiffness of their material (viscoelastic foam) composition in comparison to the Roho’s malleable flotation design.

4.6.2 Posture Perception

The participant was asked to rate the perceived postural support provided by each cushion on a scale of 1 (little or no support) to 5 (excellent support). The subject rated the USCC cushion as providing *excellent* support, the Comfort M2 as *good* support, the Roho and NCF as *fair* support and sling seating as *poor* support. The participant provided comments that further describe the quality of the support. The USCC cushion was described as “feeling molded to [her] body” with further descriptors as ‘conforming’ and ‘secure’ (see Table 4.3).

Table 4.3*Participant Rated Posture Support*

Cushion	Perceived Support	Participant Comments
USCC	5-excellent	“Excellent; feels molded to my body; completely supported; feels secure”
Comfort M2	4- good	“Like Roho cushion but pushes back more on body”
Roho 3-inch Air-Cell	3- fair	“Moderate support, sinks in, feels soft”
NCF	3- fair	“Moderate”
Wheelchair Sling Seat	2- poor	“Not completely stable”

Note. Ratings (on a scale of 1-5) and direct quotations of participant perception of postural support.

4.7 Discussion

The data provides preliminary evidence that the USCC, created by an unloaded shape-capture method provides a seating surface with pressure-relieving properties equal or superior to the off-the-shelf pressure relieving cushions to which it was compared. The USCC cushion demonstrated the lowest average and peak pressure index (PPI) when compared to all other cushions. Statistical significance was not achieved among the Comfort M2 and Roho, but was significant among the non-contoured foam (NCF) and sling seat on the measure of PPI. The USCC cushion also performed similarly to the Comfort M2 and Roho cushion and considerably better than the NCF and sling seat in the areas of quadrant distribution (SD) and contact area (%).

This study compared two categories of cushions: those that provide contour or immersion (USCC, Comfort M2, and Roho), and those that do not (NCF and sling). Those that provide

immersion performed considerably better at providing decreased interface pressure and increased pressure distribution in line with previous research (Call et al., 2017; Sonenblum et al., 2018; Tasker et al, 2014). The Comfort M2 and Roho are both marketed as pressure relieving cushions, and this study shows that the USCC cushion performed similar, and by some measures, better than these cushions in providing pressure relief and support

The USCC (and NCF) cushions used for this study consisted of *firm* grade Sunmate foam material. Typically, this grade of cushion is commonly applied to custom-contoured wheelchair backrests, while *medium* or *medium-firm* grades are used on seats. The Comfort M2 and Roho cushions consists of substantially softer surfaces than the USCC. It appears likely, that a softer foam grade for the USCC would have provided added improved pressure relief.

While this study did not directly compare the USCC to traditional loaded shape capture methods, it is clear that the novel unloaded shape capture method is feasible, provides impressive pressure relief, and postural support. Comparing the USCC to the flat NCF cushion highlights the importance of contour as a pressure-relieving component of seating systems, as noted in Table 4.4.

These results mirror the Tasker et al. (2014) study in which a loaded custom-contoured design provided improved pressure relief and comfort compared to an off-the-shelf contour design and flat baseline block all consisting of the same material. Comparing the performance of both the loaded and unloaded shape capture methods to their respective baseline data, in the absence of a direct comparison, may provide clues for how these methods compare to each other. The following hypothesis for this comparison states: *An unloaded custom-contoured cushion will result in greater pressure relieving improvements over baseline, when compared to the pressure relieving improvements of a loaded custom-contoured cushion over baseline.*

Table 4.4*Non-contoured foam (NCF) vs. unloaded shape-capture cushion (USCC) Comparison*

	NCF	USCC	Change (%)
Average pressure	62	36.5	41
PPI	>200	130.6	> 34.7
Quadrant distribution SD	21.6	15.3	29
Contact area (%)	52.93	73.93	39.7

Note. This table demonstrates the amount of improvement USCC has over NCF baseline in percentage of change.

The study by Tasker et al. (2014) suggests the contact area (cm squared) of the loaded shape-capture method (mean = 940) increased by 35.7% compared to baseline (mean = 605.02); while the PPI (mean = 15.31) decreased by 44% compared to baseline (mean = 27.35). The present study shows the contact area of the USCC improved almost 40% and reduced PPI by a minimum of 34.7% as compared to a flat cushion composed of the same foam material.

Accuracy of the PPI for the NCF baseline cushion in the present study is limited, as the pressure sensor readings under the ITs hit ceiling outputs of 200 mmHg. The true PPI for this area is believed to be substantially higher, beyond the 200 mmHg reported, signifying that the reduction in PPI of the USCC may be greater than 34.7%.

The USCC cushion presented with superior perceived postural support when compared to all other cushions, which is not surprising as it consisted of the firmest surface material. This outcome adds additional value to this cushion design as it might provide an optimal balance of

pressure relief and support for populations with postural challenges, for whom custom-contoured seating is commonly recommended (Petito & Young, 2011).

While not a crucial construct of this study, cushion weight is an additional property worthy of comparison since wheelchair weight can have a substantial impact on mobility. Reducing the combined weight of a wheelchair and cushion can contribute to the preservation of shoulder joint integrity and ease of wheelchair handling (Cowan et al. 2009). While cushion weight is not typically a priority for individuals in need of a custom-contoured seating system, weight reduction is generally beneficial for any wheelchair configuration. Among the three pressure relieving cushions, the USCC was the lightest at 3.4 pounds, which was 1.9 pounds lighter than the Comfort M2, and 0.7 pounds lighter than the Roho.

Overall, the USCC cushion provided average and peak interface pressure readings similar to the next best performing Comfort M2 cushion. The USCC provided the highest postural support scores and lowest weight. Furthermore, the USCC unloaded molding method eliminates the seating simulator and bead-filled bags needed for the molding process of traditional loaded custom-contoured seating, which may reduce time and cost.

4.7.1 Limitations

Findings from this single-subject pilot study are not generalizable, but show that USCC appears to be a feasible alternative to traditional shape-capture methods and off-the-shelf pressure relieving cushions, while also providing postural support and low weight. This outcome provides justification for further research and exploration of the unloaded shape-capture method as a viable approach to improving the accuracy and interface pressure relieving aspect of custom-contoured seat design.

Pressure mapping is not a definitive tool for determining the effectiveness of pressure relief or pressure management. Rather, the measures of average pressure, PPI, contact area, and pressure distribution serve as proxies of immersion, tissue deformation and vascularization in the absence of actual pressure prevention outcomes. Future research should include larger samples sizes, comparison against traditional shape capture methods, and actual pressure occurrence outcome measures.

Two internal validity issues are present within this study. This includes the lead researcher as the primary data gatherer, which introduces the possibility of bias toward the unloaded shape capture method. The second issue concerns the able-bodied participant presenting with good postural control, typical muscle tone, and no apparent orthopedic deformities. While the presence of able-bodied participants is common in this area of research, participant selection should reflect the physical characteristics of those typically prescribed custom-contoured seating systems.

4.7.2 Contributions/Implications to practice

Complex seating needs such as those associated with upper motor neuron lesions and orthopedic deformities pose challenges for clinicians seeking to find solutions that provide an optimal level of comfort, postural support and pressure relief. This population is often at-risk for pressure injury due to limitations in independent pressure relief management. A goal of seating prescription usually consists of a holistic systems approach in which education, caregiver support, and equipment/devices all play an important role in promotion of tissue health and function. For wheelchair users, the seating system plays a crucial role in maintaining this balance. The unloaded shape-capture method appears to demonstrate potential as an alternative

to traditional loaded methods, resulting in a lightweight, posture supporting, and high pressure relieving seating system.

4.8 Conclusion

This study analyzed data gathered from a pilot trial in which key characteristics of a custom-contoured wheelchair cushion designed using a novel unloaded shape-capture method and handheld 3D scanning technology were compared to off-the-shelf pressure relieving cushions and a baseline non-contoured cushion of the same viscoelastic material. Dependent variables consisted of interface pressure, as measured by pressure mapping technology, and participant experience of postural control. The unloaded shape-capture method performed similarly to off-the-shelf pressure relieving cushion in the areas of evenness (quadrant distribution) and contact area. Furthermore, it performed superiorly in the areas of peak and average pressure, as well as postural support, and comfort, despite being the cushion made from the firmest material in this comparison group

These findings suggest that the unloaded shape-capture method may not only be a viable method of creating custom contoured seating that eliminates the use of cumbersome molding bags and seating simulators, but may provide superior pressure relieving performance when compared to what is often considered the ‘gold standard’ of pressure relieving off-the-shelf seating systems, without compromising postural support or weight. These results justify further exploration of this technology in research involving larger sample sizes of participants for whom custom contoured seating is intended.

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Appendix A

Raw peak pressure index data for all five cushions

Sling Seat	Non-Contour Foam	Permobil Comfort M2	Unloaded Shape-Capture Cushion	Roho
200	200	111	128	137
200	200	90	169	200
200	200	76	169	108
200	200	139	95	130
200	200	200	89	200
200	200	200	89	89
200	200	200	100	200
200	200	102	167	183
200	200	65	167	73

Note. Peak pressure index (PPI) consisting of nine pressure sensor readings of highest pressure area for each cushion. Readings presented in mmHg.