The case for active safety for power wheelchair users with spinal cord injury.

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INTRODUCTION

Scope of the problem: Complex Rehab Power Wheelchairs (PWC) are critically important assistive devices for Veterans with spinal cord injury (SCI) which provide mobility independence and increase quality of life. To do this, they must be compact and agile for use in the community. Even optimally configured PWC's can prove dangerous during daily operation and lower extremity (LE) injuries can occur when the feet of users who cannot feel, see or easily reposition their LE are mispositioned on the footplates. Constant attention to foot position increases cognitive and visual load, which can distract from wheelchair operation [1]. Paralysis limits users' ability to reposition their feet and lower limbs on their PWC footplate, potentially requiring assistance from caregivers, and systemic consequences such as spasticity, contractures, osteoporosis, and tissue health increase LE injury risk.

The impact of injuries due to inadvertent lower extremity displacement (ILED) nationwide is masked by deficiencies in our medical reporting systems which prevent extraction of incidence data. Kirby [2] summarized wheelchair-related adverse FDA reports in the SCI population, the most common being fractures, lacerations, and contusions/abrasions. Morse *et al.* [3] found that almost half (47.5%) of a cohort with chronic SCI sustained tibia/fibula fractures requiring re-hospitalization, with 6.7% of these due to catching a lower extremity on a doorframe during wheelchair operation. These hospitalizations resulted in long stays, medical complications and often discharge to a nursing facility. In a three-year survey, Chen *et al.* [4] reported 54.7% of wheelchair users had at least one accident and 33% of PWC users reported accidental contact with obstacles. Additionally, striking an object accounted for 4.8% of the injuries to wheelchair users treated in US emergency departments reported in a survey of the National Electronic Injury Surveillance System between 2002 & 2003 [5].

Wheelchair Design Contribution: There are several factors in PWC design which have an impact on risk of foot and lower limb injury. The optimal specifications for a PWC are achieved by considering the user's cognitive, physical condition and living space to select a configuration that meets as many user needs as possible with the least number of concessions. However, there is no such thing as a perfect wheelchair. The following features may increase risk of lower limb injuries, despite providing improved maneuverability in tight spaces.

<u>Footplate design impact on foot positioning and safety.</u> Many modern PWC models utilize center-mount legrests to shorten PWC length and create tighter turning radii to improve maneuverability. The center-mount footplates hold the feet closer together than the previously common swing-away legrests due to positioning relative to the wheels. Front wheel-drive PWCs with center-mount footplates provide the best positioning and ergonomic functionality because the wider spacing of the front wheels allows maximal footplate surface area for foot placement and containment with relatively minimal risk for the feet to come off the side of the footplate. However, mid-wheel drive PWCs are more commonly prescribed because they have the smallest turning radius, which is ideal for negotiating tight spaces. The footplate width must be narrow on these PWC because the front casters can rotate to be only 11-12" apart during turns. If designed with wider footplates to optimize foot positioning, the legrests must angle upward to clear the front casters, increasing effective chair length, its turning radius, and risk that the user's feet contact the environment during tight turns. The alternative is a narrower footplate which fits between the front casters and reduces chair length but provides less foot support leaving users' feet prone to coming off the footplates. Additionally, most footplate designs do not extend the full length of the average adult male foot; and in close quarters maneuvers, toe contact with adjacent objects can pivot the foot without the user's knowledge. Center-mounting posts require a flat foot position on the footplate and inversion and eversion cannot be customized for joint contractures and spasticity (**Figure 1**).

Figure 1: Center-mount footplate demonstrating foot positioning issues.

Center-mount footplates provide scant lateral support to stop paretic thighs from externally rotating at the hip. Lateral thigh supports may fix this problem, but may not be available depending on payor source [6]. Some PWCs lack fore and aft calf-pad adjustability to support the lower leg, increasing leg position instability if the feet come off the footplate.

<u>Weight-shifting in tilt-and-recline PWC:</u> Positioning in PWCs with power tilt and recline provides pressure relief for the user who cannot perform

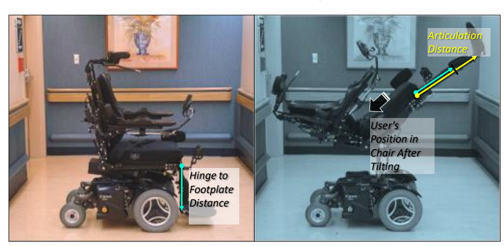

Figure 2: Tilt and center-mount leg post length

weight shifts. 45°-60° tilt of is needed to achieve effective restoration of blood flow to the ischial areas [7]. During leg rest extension, the center-mounted post lengthens as the knee hinge opens to avoid pushing the user back in the chair (**Figure 2**). The user's heels may rest on the footplate hinge during tilt creating unintended pressure points. As the PWC tilts, spasms or gravity may pull the limbs off the footrest. In optimal tilt and recline for pressure relief, PWC users' feet almost inevitably lose contact with the footplate. Thus, after return to upright, the feet may no longer sit squarely on the footplate and need adjustment.

An optimally configured PWC usually requires compromise between user positioning needs and functional mobility. The incidence of foot mispositioning during PWC use is not defined; however, when users' feet come off footplates, adverse outcomes have occurred. Foot mispositioning may occur during wheelchair mobility or at rest but may occur during or after tilt for pressure relief. This paper describes typical injuries occurring due to ILED during PWC mobility, a survey of available national reports to the FDA and a new foot position sensing system which may (1) help define the frequency of ILED and (2) prevent ILED-related injuries. Our intention is to raise awareness of ILED-related LE injuries and encourage development of active safety technologies to prevent them.

SELECT CASE REPORTS [8]

Figure 3: A: Case#1 X-ray B: Case#2 photos

During the years 2012-2019, we treated 16 Veterans with SCI for traumatic injuries caused by mispositioning of their foot on their PWC footplate. Nine Veterans required hospitalization for 6 to 326 days (mean 93 days, median 50 days). Two Veterans required partial foot amputations secondary to abrasions after dragging their feet on the ground, and one required trans-femoral amputation due to infected pressure injuries sustained secondary to casting. Seven Veterans sustained femur, tibia and/or fibula fractures when the person's foot was either caught beneath the wheelchair or caught on a doorframe, wall or other obstacle. Three subsequently developed deep tissue injuries and pressure injuries due to fracture immobilization and difficulty with achieving consistent pressure relief in casts, splints, or immobilization boots. Numerous other Veterans developed pressure injuries of the feet due to poor positioning when the feet did not sit squarely on the PWC footplate. Hospitalization for ILED-related injuries lowers quality of life for Veterans with SCI.

Case #1: A 60-year-old obese male with T8 AIS A paraplegia for 36 years caught his shoe on a doorframe while entering a building and turning in his PWC. The momentum of his PWC rotated the leg causing a spiral fracture of the tibia and fibula (**Figure 3A**). He was hospitalized for 23 weeks due to lack of home support. His fractured lower leg was immobilized, rather than receiving surgery. Bone healing was delayed with multiple complications including a pressure wound under his orthopedic boot, chest pain and anemia requiring blood transfusion. This Veteran described his experiences as follows: *"I was turning and going through a doorway and my toes caught on the edge. I came in a week after it happened. […] I went for X-ray and they told me I had a spiral break. […] I lost five and a half months of my life. I couldn't do no volunteer work, couldn't go to any family functions, missed Christmas, New Year's, my mother's birthday—again."*

Case #2: A 75-year-old obese male with T4 AIS A paraplegia for 12 years was admitted for chronic wound management, during this time he left the hospital grounds in his PWC to "get some air." While driving on city sidewalks, he had an ILED. His foot dragged under his PWC for an unknown period of time until he was notified by a bystander that his foot was hanging off his PWC in a pool of blood. His injuries included: severe abrasions of the great toe with exposed bone, superficial abrasions of the 2nd-5th toes, lacerations, and diffuse soft tissue injury. He required a partial foot amputation (**Figure 3B**). His recovery from the amputation was uneventful but occurred in the context of a complicated hospitalization for management of a pressure injury. He described the inciting event as follows: *"When my foot fell off, I probably hit a bump and I just wasn't paying attention. I caught this one because someone was beside me and they said 'Hey, your foot is off the side.'"*

Costs: The estimated cost per inpatient admission to our facility are $8280- $474,330 for the known patients with SCI and ILED-related lower limb injury. The estimated total cost of the inpatient care episodes based on Decision Support System (DSS) discharge data was $970,011 (an average of ~$200,000/year or $97,000/injury). The national VHA SCI/D System provides services to ~30,000 Veterans; thus, estimated inpatient costs may be up to ~$10M/year based on the prevalence we have seen. Injuries treated in community care are not always reported to the VHA SCI Centers, thus systemic costs, particularly for Medicare and Medicaid, are likely to be much higher.

FDA MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) DATABASE ANALYSIS

Due to the scarcity of data to elucidate specific mechanisms of injury from ILED on the footplate during wheelchair mobility [2,9], our team analyzed MAUDE database reports of wheelchair mobility-related injuries due to ILED from WC footplates submitted between 2014 – 2018 to identify injury types and evaluate MAUDE data quality

[10]. The database was searched for Product Class “Wheelchair, Powered” or “Wheelchair, Mechanical (Manual)” and the Event Type “Injury.” Report narratives were reviewed and those for wheelchair mobility-related injuries due to ILED on the footplate were extracted for further analysis. The study was exempt from IRB review.

Twenty-nine of 1075 injuries related to ILED on the footplate occurred during wheelchair mobility. All were classified as “adverse events,” and only three were also classified as “product problem reports.” Most occurred in power wheelchairs. The most common injuries reported (absolute number, percentage) were single fractures (10, 34.5%), wounds/cuts/infections (5,17.2%), multiple fractures (5,13.8%), amputations (2, 6.9%) and multiple fractures with wounds (1, 3.5%). In 24% of injuries, the injury details were unknown. In ~59% of mechanism reports, the foot slipped off the footplate unknown to the end user, followed by catching the feet between the footplate and an object (20.7%), running the feet into objects (10.3%), feet hanging over the footplate (6.9%), and the feet “banging” on the footplate (3.5%). The exact mechanism of ILED was often ambiguous in the narrative.

Mandatory manufacturer reports appeared to exhibit reporting bias indicating “end user error” as the cause without considering how user impairments in the context of product’s use and the environment may limit user ability to comply with manufacturer recommendations. Example comments include:

“Investigation revealed that the root cause of this failure mode is "improper use: device interface"…”It was reported that the patient was improperly positioned in the wheelchair leaving his right leg hanging off the side of the seat which increases the risk of potential injury if struck by an external object.”

“The patient was not” …” utilizing a ramp with a 14.7 degree slope.”

"…avoid uneven or unstable surfaces such as potholes, broken pavement, grass, gravel, and sand."

Such reports presume a choice regarding the environments and inclines being traversed, as well as full control over body positioning, which are not the case for PWC users with SCI. There are significant limitations to the MAUDE database passive surveillance system. Reports are voluntary for consumers and healthcare providers, and mandatory but not enforced for manufacturers. The dearth of reports relative to our known incidents raise concerns about compliance and awareness of this etiology of LE injuries. Despite SCI complications such as osteoporosis, fractures, wounds and amputations should not be expected outcomes of wheeled mobility use. In order to avoid harm to patients, solutions to improve wheelchair safety are needed. Product technology has the promise to help PWC user, their caregivers and families overcome the problem of ILED-related LE injuries.

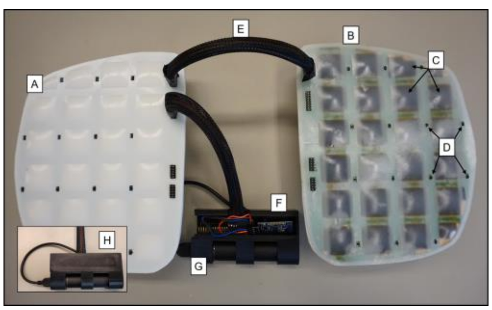

Figure 4: FoPPS System 2.4 and 2.3 footplates

A. FoPPS 2.4 - Left Footplate (Simpact 85A, urethane encapsulation, custom tint-able)
B. FoPPS 2.3 - Right Footplate (Econ 80, 80A urethane encapsulation)
C. FSR’s
D. IR Sensors
E. Left/Right Interconnect cable
F. Teensy and HM-10 Bluetooth module
G. USB battery
H. Closed electronics container
I. Interconnection pins for functional testing and calibration during prototyping.

EMERGING SOLUTIONS

Active safety measures to improve automobile control and prevent crashes now common in late model automobiles include blind spot warning, forward collision warning with automated emergency braking, anti-lock braking, lane keeping assist, and pedestrian alerts [11,12]. Autonomous navigation and auto stopping are commercially deployed in mobile robots, such as pharmacy delivery systems in hospitals [13]. However, “smart” wheelchairs utilizing sensors to achieve active safety for PWC users are still not a commercial reality today [14].

Our interdisciplinary team created a low-cost, PCT-pending [15], smart wireless footplate pressure and position sensor (FoPPS) [16] (**Figure 4**) which monitors foot position and detects changes in force distribution and proximity due to inadvertent foot mispositioning during PWC use with a goal of addressing the unmet clinical need for real-time prevention of lower limb injuries during PWC use. The innovative FoPPS footplate overlay encapsulates 23 force-sensing resistors (FSR) and 14 infrared (IR) distance sensors in an array designed to fit precisely within each footplate borders. The sensors transmit foot pressure and position data at 10 Hz with Bluetooth Low Energy radio to an iOS application (**Figure 5**) which was developed to notify users of vulnerable foot position. The FoPPS system is now ready for testing by PWC users with SCI in the typical conditions and activities of daily living (ADL), e.g. driving over rough terrain or pressure relief using tilt-in-space which can cause ILED from the footplates.

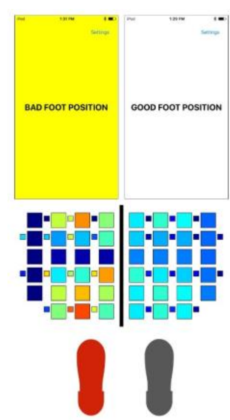

Figure 5: FoPPS iOS Application Interface Options

Safe wheelchair use currently depends on educating users on safe operation technique and consistent implementation of what was taught. This requires the user to have intact vision, cognition and impulse control [17,18]. Development of smart footplate position sensing and feedback will serve as the basis for developing active safety interventions (**Figure 6**) to address the unmet clinical need for real-time prevention of lower limb injuries during PWC use. Additionally, widespread use of the smart wireless Footplate Pressure and Positioning Sensor (FoPPS) system will help determine the incidence of such lower limb injuries and near misses. Active safety interventions should be developed and tested to improve PWC safety.

Figure 6: Conceptualized option for obtaining help with ILED.

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