The Kalogon Orbiter Smart Cushion: Whitepaper

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Background and Technology Considerations

60,000 Americans die annually from pressure injuries (PI) and PI complications [1], making pressure injuries one of the leading causes of preventable death in the United States. PIs develop through prolonged and unmitigated pressure and shear applied to the skin when lying down or remaining seated. Individuals and wheelchair users with impaired mobility, sensation and/or circulation are particularly vulnerable.

When seated, applied pressure compresses the vessels that supply blood, nutrients and oxygen to tissues around the prominences of the pelvis, lower spine and femurs. If the capillaries that supply these tissues are compressed for long durations, blood flow can be restricted, or occluded. When blood flow is limited for long durations, the deep tissues in the affected regions begin to necrose and die, eventually leading to development of a PI. Pressure injuries are staged in four levels (see Figure 1). If allowed to progress, a PI can result in life-threatening complications as the dead tissues build deeper into the layers of fat, fascia, and muscle. Further complications of a pressure injury include: sepsis, exposure and destruction of ligaments, tendons, cartilage, bone and nerves, as well as placing nearby internal organs at risk.

Stage 1: Areas over bony prominences become red and potentially painful. Top layer of skin is not broken.

Stage 2: Partial thickness loss of the dermis with potential top layer and epidermis rupture. May present as a blistered surface.

Stage 3: Full thickness loss of epidermis and dermis of the skin. Subcutaneous fat layers beneath the skin become exposed. Requires medical attention and intervention.

Stage 4: Reaches the deep tissues below the skin and subcutaneous fat layers - exposes muscles, ligaments, cartilage and bone. Requires medical interventions [2].

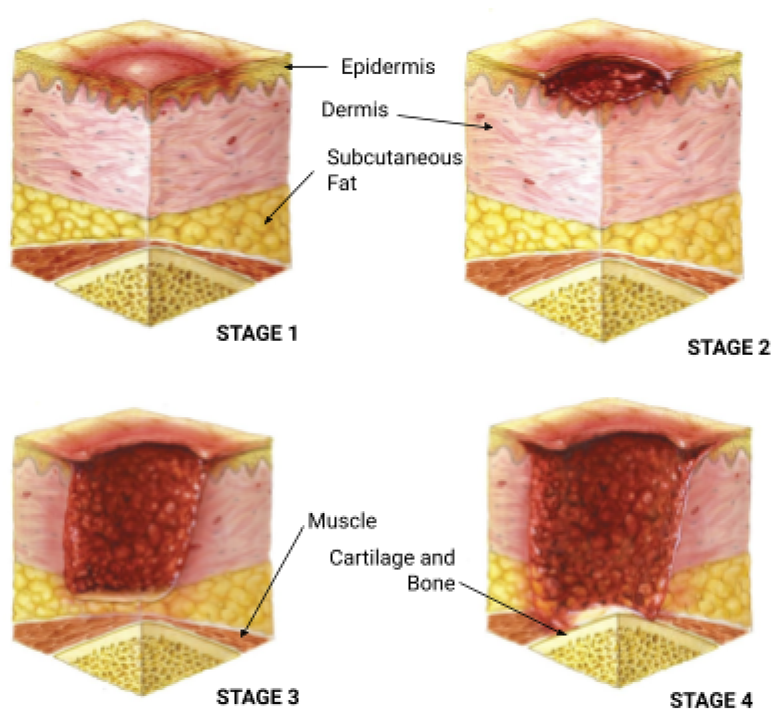


Figure 1: Staging of a Pressure Injury as referenced by Zulkowsi (2015)

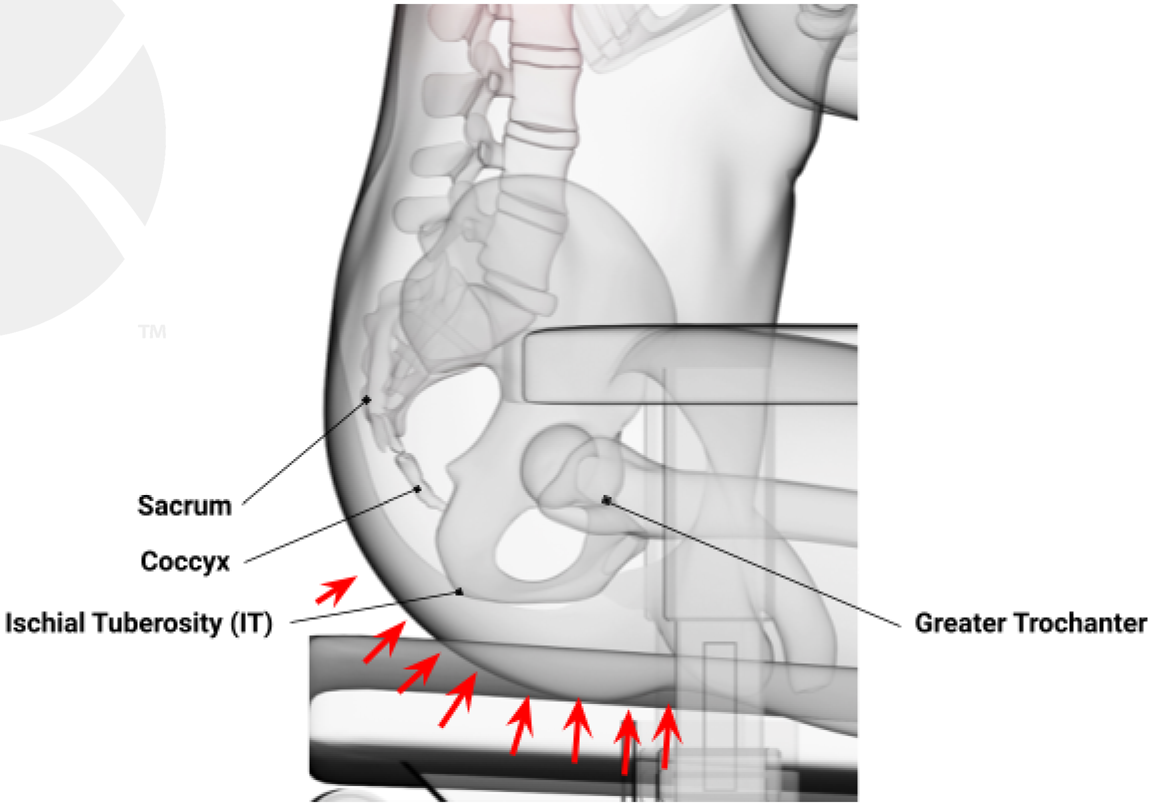


Figure 2: Internal structure of the pelvis, femur, and where pressures are applied by the seat when properly seated.

Besides the medical implications of a PI, one's quality of life becomes greatly impacted. Depending on severity, pressure injuries can take years to heal (a stagnating injury), require surgical intervention, and lead an individual to spend most of their time healing in bed [3]. For some, a wheelchair is their main method of mobility, meaning the steps needed to heal PIs such as bed rest significantly diminish one's autonomy and life. Their ability to perform ADLs (activities of daily life) becomes restricted for more severe cases of PI. ADLs can include the ability to eat, bathe or perform at home activities independently. Social outings, occupational goals and leisure activities can become severely limited during the treatment of a PI. In general, developing a PI can affect independence, mental health, require thousands in out-of-pocket expenses and significantly socially and physically isolate those affected.

Each year, 2.5 million Americans develop a pressure injury, joining the millions more experiencing the pain and negative life impacts of a PI [1]. The number of those at risk is likely to increase as the effects of the global COVID-19 pandemic become realized. Institutions and individuals incur significant financial costs during the course of treatment for PIs. The costs of treating a single PI in the US can range from $37,800 to $70,000 depending on severity, with total costs for treating pressure injuries in US healthcare facilities estimated at $11 billion annually [4]. Further, over 17,000 lawsuits are filed annually as a result of pressure injury development, often targeting nursing homes and hospitals [1]. Due to the financial, social and medical impacts of developing and treating a PI, preventing one from forming in the first place is paramount to preserving one's quality of life. Kalogon's technology aims to create the protective conditions necessary to prevent such injuries, and ensure those who rely on a wheelchair for their mobility can do so with reduced anxiety from the potential risk of developing a PI.

The At-Risk Population

Each day, the average American spends six to eight hours seated [5]. A well cushioned couch or office chair may feel comfortable at first, but over time a general unease or discomfort in the lower back, buttocks, and thighs begins to develop. Often this discomfort manifests as 'aching' or 'tingling.' Aside from general joint discomfort, these sensations derive from the pressure one applies from sitting, which constricts blood flow and therefore oxygen supply through the capillaries of the tissues surrounding the pelvis and femurs. The body registers this decrease in blood flow as an aching feeling, which necessitates repositioning to alleviate. Changing positions decreases pressure and restores nominal blood flow in the affected regions of the body. The process of routinely relieving and redistributing pressure is known as pressure offloading, and is meant to ensure the tissues of the buttocks and thighs remain healthy and perfused with blood and oxygen.

Sensations of discomfort are critical to maintaining tissue integrity. Without regular pressure offloading blood, oxygen and nutrients supplied to the tissues can become disrupted. For those with intact sensation, mobility and circulation these adjustments are performed unconsciously, ensuring sufficient blood flow to keep the tissues healthy. This is not the case for everyone. The average wheelchair user spends 10.6 hours of each day seated [6]. For those with impaired sensation or who completely lack sensation, the urge to reposition may be low or potentially not felt at all. For those with impaired mobility, even if they sense the need to reposition they may not be able to do so. Pre-existing conditions that impact circulation further increase the PI risk, regardless of seated position.

Pressure injuries are not a rare condition, as any individual with limited mobility is at risk for developing a PI. For example, roughly 95% of those in the SCI (spinal cord injury) community are expected to have, or currently have, a PI. For those living with a SCI their risk for developing a PI is exacerbated by the fact that they experience all three of the primary risk factors; impaired sensation, impaired mobility and impaired circulation [3]. Generally, those seeking geriatric care are also at high risk for pressure injury, with nursing home PI rates at 7% to 23% for individuals several months into their stay [7].

Pressure Management

Despite the prevalence and severity of PI seen throughout the United States and globally, a four-year study argues that 91% of pressure injuries are preventable [8]. Prevention is achieved through a myriad of factors, including skin checks/observation by the affected individual or their care team, as well as implementing consistent pressure reduction techniques. Further, the use of technologies to improve blood flow in high-risk areas and preventing microclimates (damp, warm environments) that promote bacterial growth can help protect against PI development.

Regardless of the reason, anyone that routinely uses a wheelchair is at risk for developing a pressure injury. To reduce this risk pressure offloads are performed as the primary method for disrupting and redistributing applied pressures, allowing for blood flow to remain at normal levels. Common recommended offload techniques involve either leaning over to one side or leaning forward as if to reach for an object on the floor. These movements allow the applied pressure to be shifted from the pelvis to the thighs, which are less susceptible to PI development. For those unable to perform offloads independently, power-wheelchairs with tilt-in-space functionality (discussed below) can be prescribed. Additionally, family members or care providers often aid in the pressure offloading process. For such cases, PI prevention recommendations typically include limiting wheelchair use to reduce pressure on sensitive bony prominences. As mentioned prior, limited wheelchair usage significantly affects one's ability to engage in social activities, and so many individuals try to maximize the time they can spend in their chair.

Figure 3: From Left to right: 1. Example of a lean-forward offload 2. Individual performing a leaning side-to-side offload 3. Example of a "lift-off" offload [9].

The intent of the off-loading methods presented in Figure 3 is to disrupt, redistribute, or move constant pressures away from the ischial tuberosities (ITs) and sacrum (anatomical diagram shown in Figure 2). A leaning-forward offload redistributes pressures away from the buttocks to the thighs. Weight shifts from side to side aim to oscillate pressure between the ITs. Lift-off reliefs are used to remove pressure off the entire seated surface. Lift-offs, while the most effective at eliminating interface pressure, often are difficult to perform for those with limited upper body strength and require strong core and tricep muscles. As such, weight shifts have been shown to be preferred, especially for those individuals that may have difficulty performing a leaning-forward motion. A study of routine pressure relieving motions by wheelchair users concluded that while lean-forward and 'lift-off' offloads were performed an average of 0.4 times per hour (in other words, less often than once per hour), weight shifts were more common, at an average of 2.4 times per hour (or roughly every 25 minutes) [9].

Practicing consistent and proper pressure offloading is critical for preventing PI development. However, several studies indicate a significant number of wheelchair users do not perform them properly per clinical guidance. A study by Stockton et. Al. (2002) concluded that, ***even though many wheelchair users surveyed had the ability to perform offloads, a majority (54.7% of 136 surveyed) moved, shifted or performed offloads less than once per hour.*** Just 20.8% reported moving at least once per hour. Clinical recommendations generally prescribe performing offloads once every 15 minutes. As such, both the Sprigle and Stockton studies show that the evaluated groups performed offloads significantly less often than recommended.

Some models of electric or complex rehab chairs provide 'tilt-in-space' functions to help perform one's offloads, allowing the user to tilt back or recline their wheelchair seat for a period of time (shown in Figure 4). The tilted position is intended to transfer some of the user's weight from the pelvis to the upper back during an offload. These chairs can provide pressure offloads for individuals with tetraplegia or those that otherwise cannot perform offloads unassisted. These systems tend to cost thousands, to tens of thousands of dollars for the user or care provider, making them out of reach for those without access to disability or medical insurance. While the tilt-in-space function is specifically prescribed for individuals that have difficulty performing offloads, a study of usage by the SCI community suggests that many individuals are not using this feature as recommended for reducing PI risk. While a chair-tilt angle of at least 45 degrees should be maintained during an offload to meaningfully offload the seated surface, the study found most of the participants either only reached a 15 degree angle to improve comfort or otherwise did not use the feature as frequently as recommended [11].

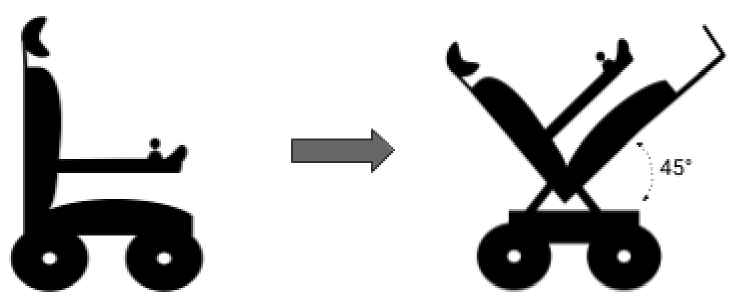


Figure 4: Compex rehab chair performing a 'tilt-in-space' offload

Recommendations for the duration needed when performing pressure relieving offloads differ based on varying clinical guidance, though most wheelchair users are advised to offload for 15 to 30 seconds at a time [9]. As offloads are intended to create the conditions for blood to reperfuse damaged or oxygen-starved tissues, these offloads and weight shifts must last enough time for the capillaries to refill and supply necessary nutrients throughout the sitting surface of the individual. A study of 50 individuals' blood perfusion below the skin concluded that, for those evaluated, a 30 second offload is generally not long enough to allow for oxygenation of the tissues to recover to unloaded (unseated) values. Rather, an average of nearly two minutes (111 seconds) was shown to be required, well beyond the standard clinical recommendation [12]. For those preferring the lift-off method of offloading, maintaining a nearly two minute lift would be especially difficult. ***For this reason in particular, Kalogon's technology is designed to assist users in performing weight shifts at defined intervals above this two-minute threshold.***

These studies highlight what care providers and clinicians in wound management know well. Many individuals who rely on wheelchairs for their mobility needs are either unable to perform effective pressure offloads or do not offload for enough time or frequently enough to adequately perfuse the tissues in susceptible areas. Further, some of those prescribed tilt-in-space wheelchairs do not consistently utilize the feature effectively enough to allow for reoxygenation of the affected tissue. Smart seating technology capable of augmenting these weight shifts and offloads is necessary to help manage wheelchair users' pressure offloading needs.

Current Solutions do not Address the Problem

Static wheelchair cushions are generally designed to redistribute a user's applied pressures and reduce PI risk via two distinct methods. One mode (offloading/contouring method) aims to remove pressures from sensitive areas. The second type (immersion method) distributes a user's applied pressure throughout the largest possible surface area through the use of a deformable medium.

Offloading cushions tend to provide cavities or contouring around bony prominences in the pelvis. Distributive/immersion cushions use air, foam or gel to disperse pressure [13]. Regardless of the method, most wheelchair cushions today are static. They do not adjust applied pressures over time without user intervention through manually offloading. These cushions are designed to redistribute or offload pressures in certain regions, rather than aid in actively redistributing static pressures. This means that if pressure-relieving offloads are not performed by the individual using such a cushion, localized pressures remain fixed in place.

In some cases, these cushions can impede the ability of the user to fully perform a pressure offload. For instance, an air-flotation cushion may tend to apply pressure to the buttocks of an individual performing a lean-forward offload. As the user applies more pressure to their thighs this tends to force air toward the back of the cushion and load the pelvis. *Further, from our* *interviews with end users and experts, this phenomenon makes transfers, or the movements required to leave a wheelchair, particularly difficult for some.*

As air-flotation cushions do not have rigid structures to hold the user in place, those with limited sensation may feel a lack of stability. Cushions that utilize gels or contouring are more resilient to this behavior. Some studies have looked to quantify whether one type of cushion is more effective than another for reducing PI risk. As shown in the Stockton et. Al (2002) study of the 65 individuals surveyed using static air-flotation or gel cushions, two-thirds (67.6%) had experienced a PI prior to the survey, and one-fourth (24.6%) had a PI at the time of the survey. 48% of those surveyed while on a static air-flotation cushion were stated as currently experiencing a PI. Regardless of the cushion type, both populations surveyed experienced significant levels of PI occurrence [10].

Air-flotation cushions are generally effective at immersing a user's bony prominences. However, these cushions must be properly inflated using a manual pump to an inflation state that is critical to maintain but difficult to verify. Under or over-inflation limits the cushion's effectiveness. These cushions tend to be susceptible to leaks, which may cause the cushion to no longer function as intended, and result in the client directly sitting, in some cases, on the metal or rigid seat-pan of their wheelchair. This results in a dangerous situation, as direct pressure is applied to the ischial tuberosities (ITs) and can rapidly result in PI development.

For customized offloading cushions, the cushion is specifically designed for the user through a 3D scan or mold of the client's pelvic and/or thigh geometry. This type of offloading cushion is designed to contour to the user and avoid placing pressure on the ITs. Due to the customized nature of these systems they can be difficult to properly modify after manufacture if the user gains or loses weight. Further, offloads may be difficult to perform as the cushion locks the client's pelvis in place. Misalignment of the pelvis within the cushion can therefore lead to discomfort when pressures are applied to bony prominences of the pelvis, trochanters and sacrum.

Through a review of the available cushions on the market, a customer or clinician can aim for an immersion cushion, but with the trade-off of a lack of stability. Alternatively, one can go for a rigid offloading cushion, yet this too results in the compromises of a lack of positioning variability and limited alteration options when the user's body changes. Further, ***all current options fail to address the primary cause of pressure injury - unmitigated pressure applied to the user's seated surface***. What is clear is an automatic, alternating pressure cushion is needed to ensure pressures are routinely adjusted with or without the input of the user.

Recurring Pressure Relief Requires an Active Surface

Unlike most wheelchair cushions on the market, the Kalogon Orbiter Smart Cushion utilizes a construction that can adjust the shape of its surface through powered control. Known as an active surface, the cushion provides automatic altering and adjustment of the client's applied pressures without the user adjusting their position. This technology is designed to directly target the sustained pressure applied to the bony prominences of the pelvis and redistribute pressure to less sensitive areas.

Limited variations of active surface or powered cushions outside of the Kalogon Orbiter currently exist in laboratory and market settings. In one study, through the University of North Dakota, a custom active surface cushion was developed and tested with the intent to quantify its effects on interface pressure (the pressure applied by the cushion on the IT's, sacrum and thighs) and tissue oxygenation, among other key indicators of cushion performance. The cushion tested provided the ability to inflate and deflate in three unique sequences, and adjusted interface pressures on a repeating basis. Data analysis in the study confirmed that, after 22 minutes of use, average interface pressure decreased significantly compared to baseline values for the individuals in the experiment. Notably, tissue oxygenation reacted quickly upon the onset of the alternating pressure sequences [14].

Oxygenation improvements in the tissues are critical, as a lack of oxygen supply directly results in increased risk of tissue necrosis and death. This phenomenon illustrates the need for pressure alternation as a feature in a wheelchair seating system. Since many wheelchair users do not routinely perform the offloads needed to reduce PI risk, alternating air-cushions can aid in improving blood flow and oxygenation to at-risk tissues. The Fadil study confirms this, stating ***"the study findings highlighted the positive effects of the designed dynamic air-cushion to relieve pressure on compressed areas and enhance blood perfusion similar to manual offloading approaches."***

Localized Control of Pressure Application is Necessary

The UND study further indicates that generalized alternation, often called 'A-B rotation' or 'open-loop,' does not significantly affect pressures around the ITs. Similar to the approach taken with most alternating air mattresses, these systems generally consist of multiple sets of cells connected together, so that one set inflates in the first inflation sequence, then deflates, followed by the second set inflating with the process repeating thereafter [15].

Where these types of alternating systems fall short is the inability to pinpoint where offloading or support are needed. While open-loop alternating pressure cushions can reduce pressures generally, precise control of where offloads and support are provided is critical. The pressure relieving behavior of a cushion should therefore be based on the individual's seated positioning habits and PI history to avoid applying pressure to sensitive areas. ***This is where the Kalogon Orbiter stands out. The Orbiter Cushion is the only option on the market with the ability to adjust localized pressures based on user needs without physically modifying the cushion.***

The Kalogon Orbiter Smart Cushion

From the above analysis of common PI causes, prevention strategies, and the difficulty with which those strategies are performed by many wheelchair users, an evident mismatch exists between medical recommendations for performing routine pressure relieving offloads and real-world considerations. Further, while existing cushions can be effective at distributing pressure, such cushions do not consistently aid in actively shifting one's applied pressure.

Figure 5: Orbiter Smart Cushion and Controller, hose link is disconnected for visibility

The Kalogon Orbiter Smart Cushion has been developed through nearly two years of R&D, customer interviews, clinical evaluations and consultation with our industry partners to address the gaps in PI risk reduction. The features and functionality present in our cushion have been implemented specifically to target pain-points experienced by existing users of other legacy wheelchair cushions. Through exploring the key features customers and clinicians look for in the ideal cushion, four key attributes of Kalogon's seating system were developed to form the basis of the Orbiter's functionality:

- Provide a *dynamic surface* capable of performing targeted pressure redistributions around the pelvis and thighs to reduce stagnant pressure points.
- Allow for precise *customization* by the end user, care provider or clinician to tailor pressure reliefs and support to unique individual needs.
- *Adapt* to postural, weight and seating position changes to effectively manage pressure changes over time.
- Implement a *self-checking* system, capable of detecting when to increase or decrease inflation levels, monitor for air leaks and eliminate the need for complex maintenance.

Kalogon routinely seeks input from its customer base and clinical advisers to ensure the features we provide in the Orbiter cushion match what customers and their care teams request. We developed a beta-test program for early adopters, which has provided the ability to rapidly convert customer feedback into usable features through a simple software update.

Dynamic Surface

The Kalogon Orbiter Smart Cushion periodically adjusts interface pressure on the user's seated surface by inflating and deflating five air cells within the cushion. The air cells pneumatically link to the controller, as shown in Figure 5, through a connecting hose. The controller houses the pressure control system, battery and electromechanical hardware that inflate and deflate the air cells over a timed interval. Above the air-cells is a stack-up of visco-elastic, slow recovery foam. The foam itself is contoured to dip down around the pelvis.

The combination of foam and adjustable air cells allows the cushion to combine elements of immersion and offloading cushions. The visco-elastic foam stack-up that comprises the majority of the cushion's volume provides a medium for the pelvis to immerse within. The air cells are then used to modulate interface pressures and adjust where support or pressure reductions are provided based on input from the controller's pressure sensing system.

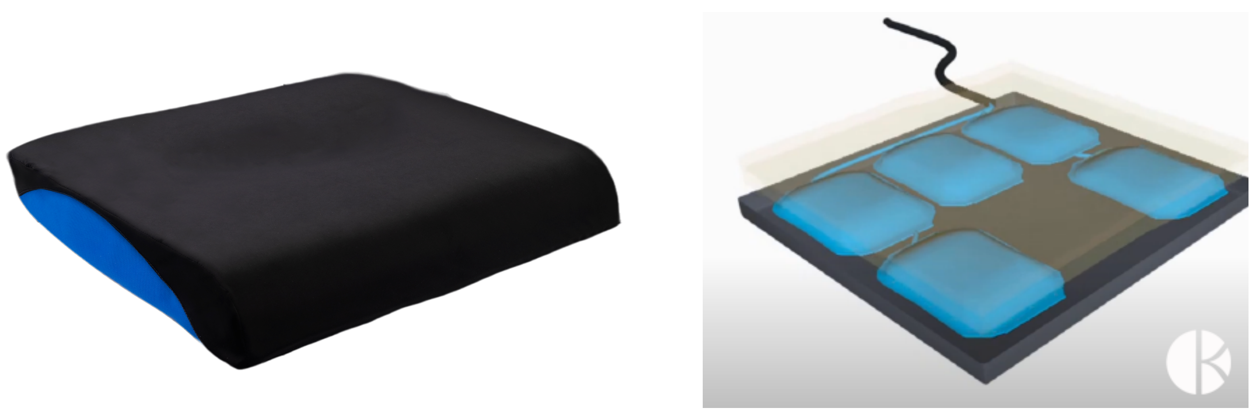
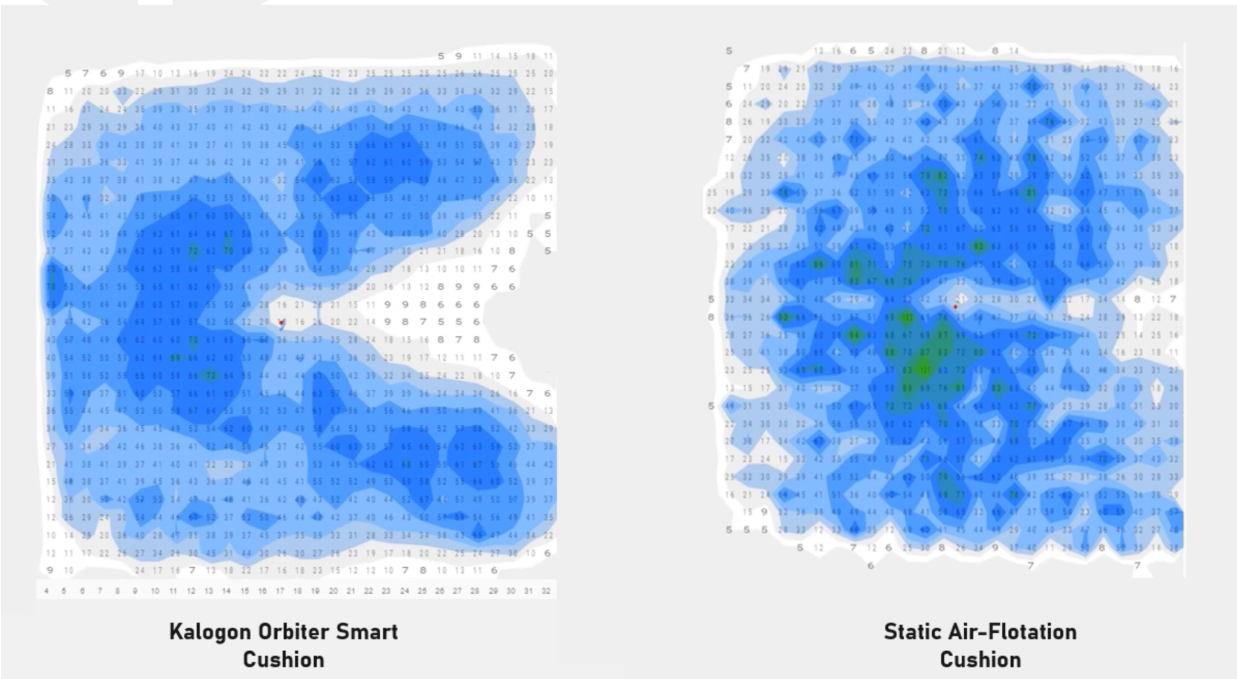


Figure 6: Orbiter Smart Cushion and rendering displaying its internal air cells beneath foam layer

The Orbiter's dynamic surface is designed to assist wheelchair users who have difficulty performing weight shifts and offloads at the recommended interval, *providing over 200 redistributions per day when set to a 3-minute cycle*. The cushion's dynamic surface is designed to bridge the gap between clinical recommendations for weight shifts/pressure reliefs and what is actually possible outside of the care setting for individuals with mobility difficulties. Additionally, the cushion can aid in assisting one's weight shifts when performing an actual offload would be difficult, such as in a car, during a social event or while asleep. A video of this pressure redistribution functionality is available at www.kalogon.com.

Evaluating weight shift effectiveness is often conducted through the use of a pressure map, which can provide a visual representation of the interface pressure between a wheelchair user and their cushion. Pressure maps implement thousands of load sensors that monitor and display interface pressure in real time. The figures below were generated from a calibrated Boditrak2 Pro pressure mapping system, used to collect data for our foam design efforts and tailor our control loop to ensure pressure redistribution is routinely provided by our cushion.



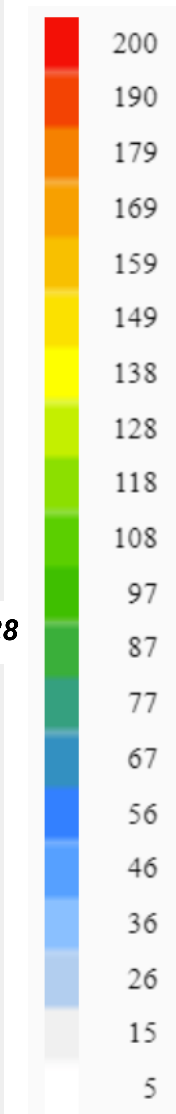


Figure 7a - User on cushion with sacrum loaded, Orbiter Dispersion Index (DI) at Pelvis: 28

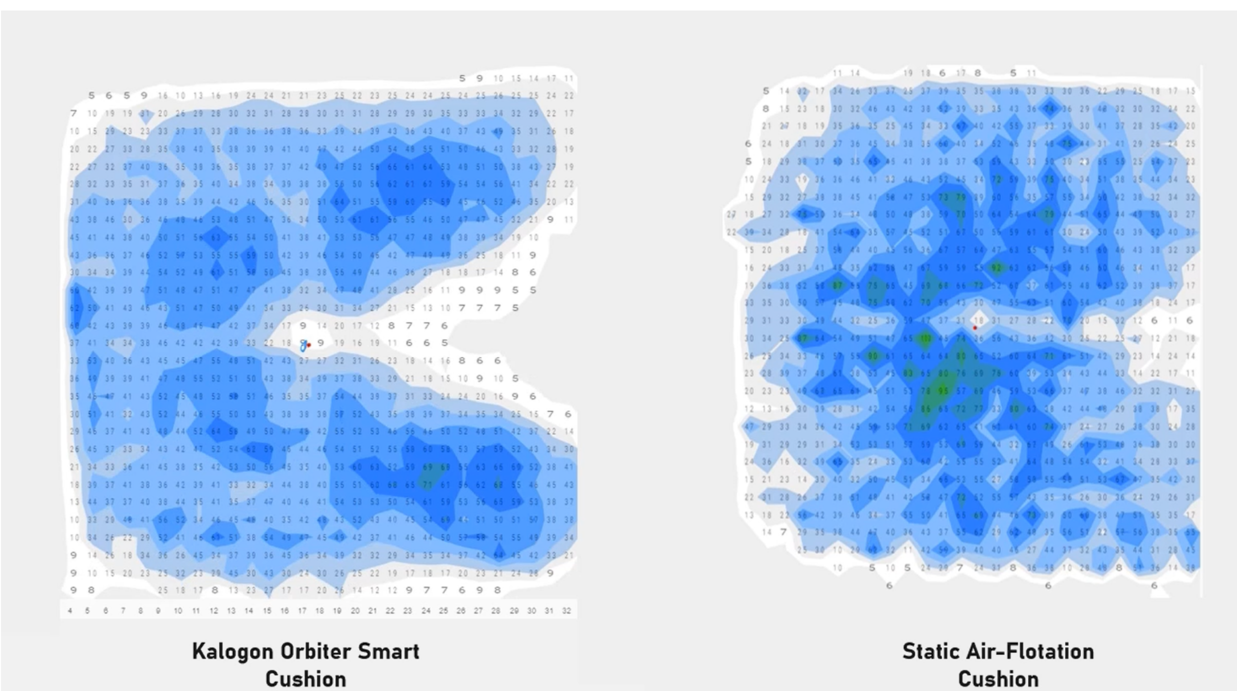


Figure 7b: Orbiter Cushion Offloading User's Sacrum, Orbiter DI at Pelvis: 25

In Figure 7 above, pressure mapping data is used to evaluate the effectiveness of the Orbiter specifically offloading the sacrum of an individual using the cushion on a manual chair. The pressure map system employs several key indicators to evaluate an offload:

- Dispersion index (DI) - Ratio between pressures applied within a bounding box and the entire seated surface. For the purposes of evaluating the Orbiter cushion, this bounding box is placed around the ITs and sacrum as a means of comparing pressure applied in this region to the entire seated surface. Generally the lower the DI value, the more effective a cushion performs at distributing pressure away from the pelvis.

- Peak Pressure Index (PPI) - Average of pressures within a bounding box. Useful for evaluating generalized areas of higher pressure seen on a pressure map.

High interface pressures at the seated surface are thought to constrict blood flow and oxygenation to the capillaries and vessels of the tissues around the pelvis. Various studies have resulted in different values for what pressure magnitude is required to occlude, or cut off blood flow. In one study, values varied from 40 mmHg (for occlusion in the shin) to 71 mmHg (for occlusion on the sacrum) depending on the region of the body evaluated (Sprigle, et. Al., 2011). As such, this suggests reducing interface pressure in localized regions can improve the ability for blood and oxygen to return to affected tissues.

Note in Figure 7 the dispersion index drops from 28 to 25 during a sacral offload. As the DI is relatively low (i.e. ~75% of the user's pressure is dispersed away from the ITs and sacrum) the user's pressure has dipped below the occlusion threshold values noted in the Sprigle study, suggesting that blood-flow should improve based on the values recorded. This pressure offload would be held for the duration selected on the accompanying app (standard of 3 minutes), referenced in Figure 9. For visualizing varying interface pressures on the surface, the pressure map provides a gradation coloring, as shown above. Figure 7 provides the legend for identifying these pressures.

To facilitate an effective dynamic surface, the Orbiter's cover is made with fabric intended to stretch in four directions. Also known as four-way-stretch material, these fabrics are used to reduce shear on the user's skin. The top layer of the cushion cover was specifically designed to stretch significantly in the presence of applied force and shear. Further, all materials used in the cover are water resistant, to reduce the risk of liquid pooling between the user and the cushion during episodes of incontinence. This is specifically intended to reduce the risk of microclimates that promote bacterial growth. The moisture wicking nature of the cushion cover' top layer ensures liquids are displaced away from the user.

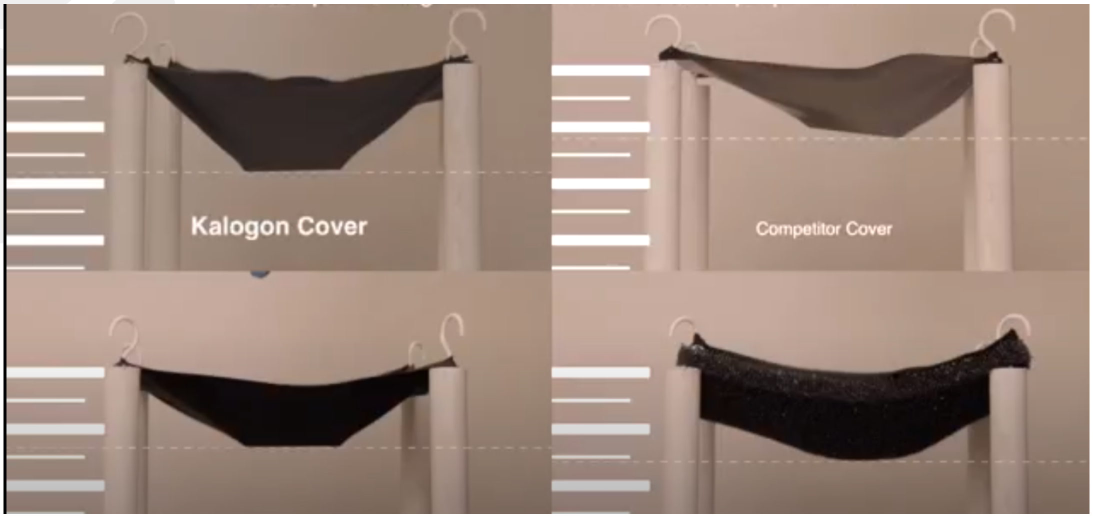


Figure 8: Example of a Qualitative Cushion Fabric Comparison Test to Evaluate Stretch.

Customization Features

The ability to sense and control where localized pressures are applied differentiates the Kalogon Orbiter from current available cushions on the market. Every individual seeking to use the Orbiter has a unique seating position and firmness preference. To accommodate, the Orbiter has the ability to tune cushion firmness in localized regions, and ensure any given region of the cushion is adjusted to the user's specific needs.

Firmness levels of the cushion's active surface can be altered through Kalogon's iOS or Android app. The app provides a settings panel that displays the firmness values, between 0% and 100%, for each of the five air cells in the cushion. Clinicians and end users can use the app to customize the relative firmness settings of the cushion and adjust the seat and pressure redistribution profile to fit their specific needs. For instance, individuals with known pressure injury can adjust the cushion's settings to allow for the affected area to remain relatively unloaded by the cushion's air cells compared to the rest of the seated surface. This mode will still ensure the other areas of the cushion continue to receive pressure redistributions.

Lastly, for those using a manual chair or who otherwise repeatedly thrust to propel themselves, the app can be used to create a mode in which the cushion provides a high dump angle. Dump angle describes the relative height difference between the front and back of a seat cushion. The Orbiter can produce a high dump when the app settings are changed to have the front of the Orbiter cushion set to a higher firmness than the back. This ensures the pelvis of the user is generally lower than their thighs, all while the redistribution mode of the active surface continues to perform its function (the leftmost image in Figure 10 illustrates this feature).

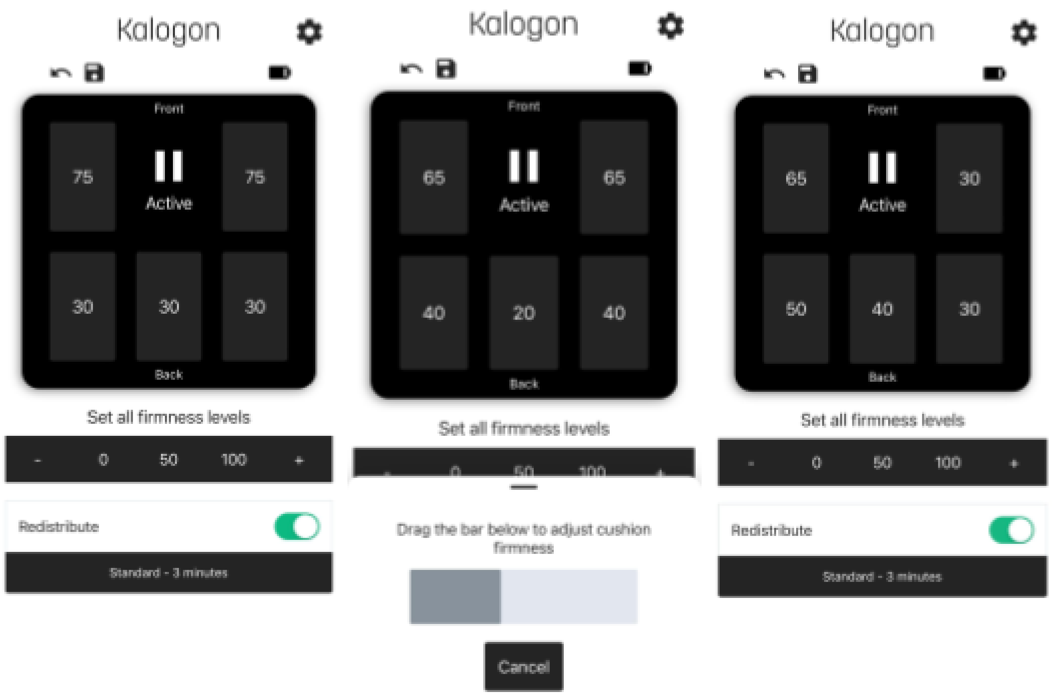


Figure 9: From Left to Right: 1. Example of an anti-thrust seat dump, 2: Example of offloading the sacrum to relieve a potential PI, 3: Example of a rightward dump angle.

Note Kalogon does not provide specific settings for reducing PI risk or comfort for the individual client. These settings are set by the user or their clinician. Some clinicians use pressure mapping to decide which settings to use, while others may use the perceived pain or comfort experienced by the user to adjust firmness settings.

Adapts to Changes in the User and the Environment

The cushion continuously monitors the pressures applied by the user in five specific regions. If the user leans in any direction, the cushion adjusts as necessary. For instance, if the user lists to one side, the cushion will detect the change in pressure and automatically inflate or deflate its air cells as necessary, as illustrated in Figure 10. This ensures that the firmness levels desired by the user are consistently maintained, and removes the need to either manually inflate or relieve air from the cushion. No manual pumps are required, as the cushion will handle pressure adjustments automatically. Settings changes can be made in the app as necessary to aid in managing seating as necessary.

Over time, if the user gains or loses weight, this change will be detected by the Orbiter cushion prompting the controller to adjust pressure as necessary. Likewise, if the user carries a large object while on their chair, the cushion's air cells will be directed to deflate slightly to avoid placing excess pressure on the user's seated surface. In a similar manner, the Orbiter cushion will turn off if the user gets up or transfers out of their wheelchair. Once the user returns and sits down on the cushion again, the Orbiter will detect this action and turn on. This ensures that if the user or their care team does not remember to turn on the cushion when the wheelchair is in use, the cushion will trigger on and function as normal.

The cushion monitors ambient pressures and adjusts to compensate. For instance, if a customer brings the cushion in the cabin of an aircraft or on a drive through a mountainous area, the cushion will detect the resulting decrease in ambient pressure that occurs. In static air-flotation cushions, this pressure change would tend to result in an overinflated state, placing excessive interface pressures on the user despite a proper inflation value on the ground. Static air-flotation cushion users who compensate by relieving air are then surprised to see their cushion has become deflated once their elevation drops. This places the user at an underinflated state, which results in an increased risk for PI development. As the Orbiter cushion can automatically detect ambient pressure changes and adjust, the user will not need to perform any kind of pressure adjustments to the cushion.

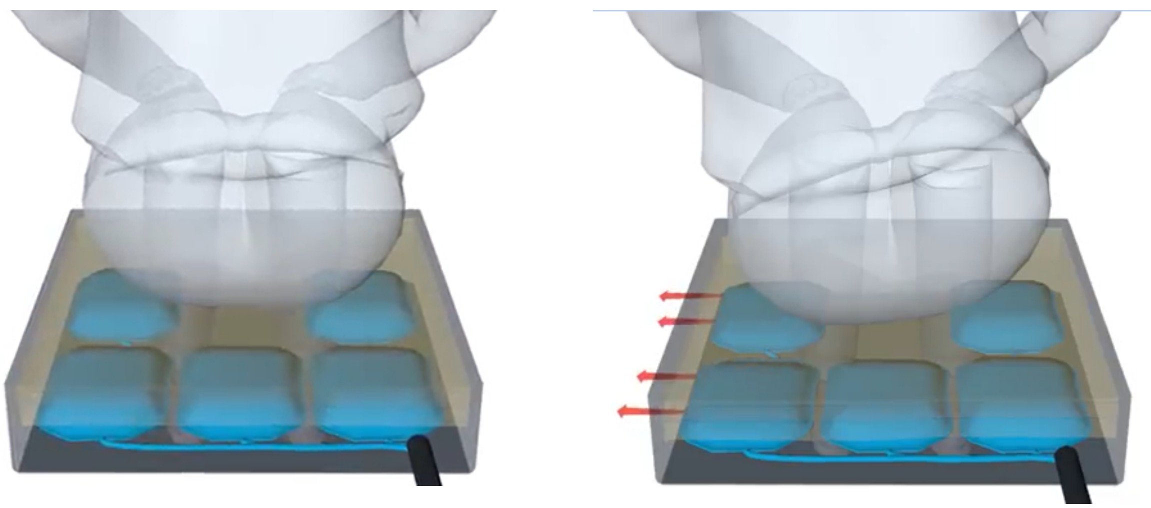


Figure 10: If leaning occurs while seated on the Orbiter cushion,the controller detects the change and adjusts air cell inflation state as necessary to compensate.

Self-Monitoring and Safety

Wheelchair cushions enable the user to go about their day more comfortably and safely. As the Orbiter cushion operates continuously while the user is seated, the cushion is designed to detect any mechanical issues and alert the user as necessary. To avoid the need for routine maintenance, the cushion runs a leak detection system to monitor the condition of its air cells. In the event of a leak, such as from an installation error or damage to an air cell, the Orbiter's control unit will detect the issue and begin pumping air into the affected zone.

In an extreme case, if the pneumatic connection between the controller and the cushion becomes disrupted, the controller would detect the leak and alert the user. During this event, the air within the cells could leak out. Unlike a cushion that relies solely on air to provide support, if the air cells fully deflate the user would still be supported by the foam layer of the cushion. The intent of the self-monitoring system in general is to ensure the customer is confident the system is modulating interface pressure regardless of the user's interaction with the cushion.

Figure 11: Controller and cushion installed on a manual wheelchair

The controller uses indicator lights to inform the user of its status. A green LED (as shown in Figure 11 above) will illuminate during normal function. If the self-monitoring system detects a leak, low battery or other issue the cushion's amber LED will signal, along with an accompanying chime to alert the user. The visual and audio alert sequence varies depending on the type of issue detected.

Clinical Case Study

Below is a highlighted case study of our cushion in use to manage and treat a stage IV pressure injury. The detailed study is referenced here.

Background

Ms. Z. is an 53-year old female with a spina bifida related L1 lesion resulting in complete flaccid paralysis and hydrocephalus (shunt in place). She presents with a 2-year-old chronic, slow healing stage 4 sacral pressure injury. Ms. Z. is single, lives independently, and is partially independent with performing ADLs, requiring some assistance of a caregiver for catheterization and transfers. She has a sigmoid diverting colostomy in place which required home health care. Ms. Z. reports no history of tobacco, alcohol, or illicit drug use. Until the age of nine she ambulated with braces and forearm crutches, then transitioned to a manual wheelchair. In June of 2020 she became a full-time powerchair user primarily due to reported shoulder dysfunction and upper extremity sensory and motor impairments resulting in a cervical spine fixation.

Eventually Ms. Z. developed a stage 4 sacral pressure injury. This wound was described as quarter-sized and covered by a layer of eschar. During this time the PI had not fully closed, and was self-managed at home using Calazime and a simple dressing. In March 2020, after an unrelated month-long hospitalization she was discharged home. During a transfer her mother noticed that the quarter-sized wound's eschar covering was cracked open and draining.

Significant past medical history includes:

- Spina bifida (paraplegia)
- Neurogenic bladder
- Hydrocephalus
- Chronic sacral pressure injury (stage 4)
- Recurrent kidney and bladder infections

Significant past surgical history includes:

- Multiple C1-C3 stabilizations
- Normal pressure hydrocephalus shunt (ventriculoperitoneal)
- Cardiac catheterization and pacemaker placement
- Sigmoid diverting colostomy

The Switch to Kalogon's Seating System

Throughout the two years of wound care and associated medical procedures, Ms. Z.'s stated goals included increased time in her powerchair, improved independence with self-care and a return to social activities including attending church, concerts, eating out, engaging in rehabilitation of both shoulders and a return to driving. Besides the medical consequences of the stage 4 sacral pressure injury, for Ms. Z., the most significant impact of her wound was loss of independence, time confined to her bed, disconnection from social activities and loss of self-efficacy. While in the powerchair on her initial seating system, her self-reported back pain was an 8/10 even for short periods of time.

Ms. Z switched to use of Kalogon's smart cushion in July 2021 after consulting with her wound care clinician. Ms. Z reports her initial trial on the Kalogon cushion enabled her to comfortably sit in her power chair for 6 hours. Eventually she progressed up to 8 hours in her chair with a "break" in-between, reporting no greater than 6/10 back pain. Over the course of roughly 10 months her stage 4 pressure injury fully closed. Now that her wound has closed and is stable, she feels her independence has returned.

"Now I can go and do what I have to on the Kalogon cushion."
-Ms. Z

In addition, Ms. Z. is thrilled about the "Sit-to-Wake" function of the Kalogon cushion, which turns on the cushion when she sits down. Given her upper extremity weakness, on-going shoulder and back pain as well as her lack of sensation, she has difficulty in implementing her regular off-loading/weight shift program while in her power chair. The cushion's automatic pressure redistribution feature, while not replacing offloads, has helped to aid her pressure relief regiment. Due to this, Ms. Z. states that this feature and the cushion have helped decrease her concern and anxiety of developing new pressure injuries or re-injuring her closed pressure injury.

Figure 12 details the progression of Ms. Z's injury before and during the use of a Kalogon Orbiter Smart Cushion. The timeline completes at the closure of her stage IV pressure injury.

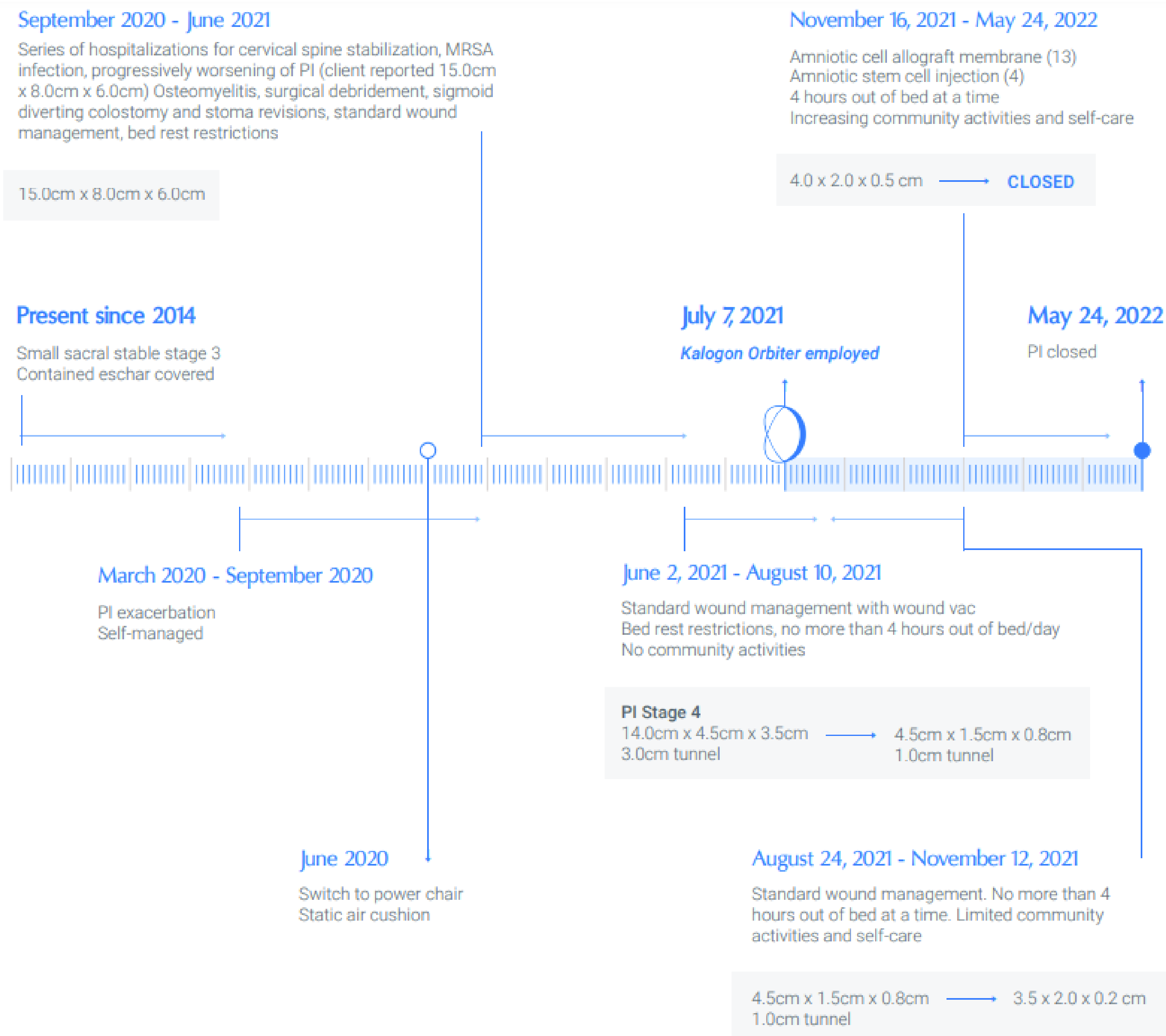


Figure 12: Timeline and Pressure Injury Progression noted during Kalogon Orbiter Case Study

Kalogon Inc.

Our mission:
"Kalogon addresses the negative effects of prolonged sitting.”

Our Vision:
"Founded by former SpaceX engineers Kalogon is applying cutting edge technology to revolutionize the way the world sits"

- Tim Balz, CEO - Kalogon Inc.

Disclaimer statement

These statements have not been evaluated by the Food and Drug Administration. Please consult with your clinician prior to ordering a cushion from Kalogon to determine your needs, optimal off-loading processes and habits, and the best practices for you to follow.

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