Disclaimers

- This presentation is not designed to promote any particular brand of cushion.
- This presentation is not making recommendations to use any particular brand or style of cushion.

Pressure injury prevalence

- A Leading Cause of Preventable Death
- Based on a prevalence of 12.9%, the total cost of pressure injuries in Australian public hospitals was $9.11 billion (2020)
- Cost to Heal – Stage II $44,000 Stage IV $105,000 upward
- Approx 60,000 Americans die annually from PIs and their complications (Agency for Healthcare Research and Quality, 2014).
- Over 4000 HAPI occur in Australia every year

(Yap, G. & Melder A. 2018. A review of pressure injury rates in Australian hospitals: A Rapid Review. Centre for Clinical Effectiveness, Monash Health, Melbourne, Australia.)

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> Int J Nurs Stud. 2022 Jun:130:104191. doi: 10.1016/j.ijnurstu.2022.104191. Epub 2022 Feb 10.

Pressure injuries in Australian public hospitals: A cost of illness study

Son Nghiem [1], Jill Campbell [2], Rachel M Walker [3], Josh Byrnes [4], Wendy Chaboyer [5]

Anyone who sits for extended periods is at risk for pressure injury

On average, someone in the US sits about 8.3 hours a day

- People who use wheelchairs spend more, with 11.9 hours a day seated

- Of a US Rep population, 16% have a disability that requires them to sit for extended periods of time

- Pressure injuries are seen in more than 1 in 10 in a US Rep Population and in half of wheelchair users.

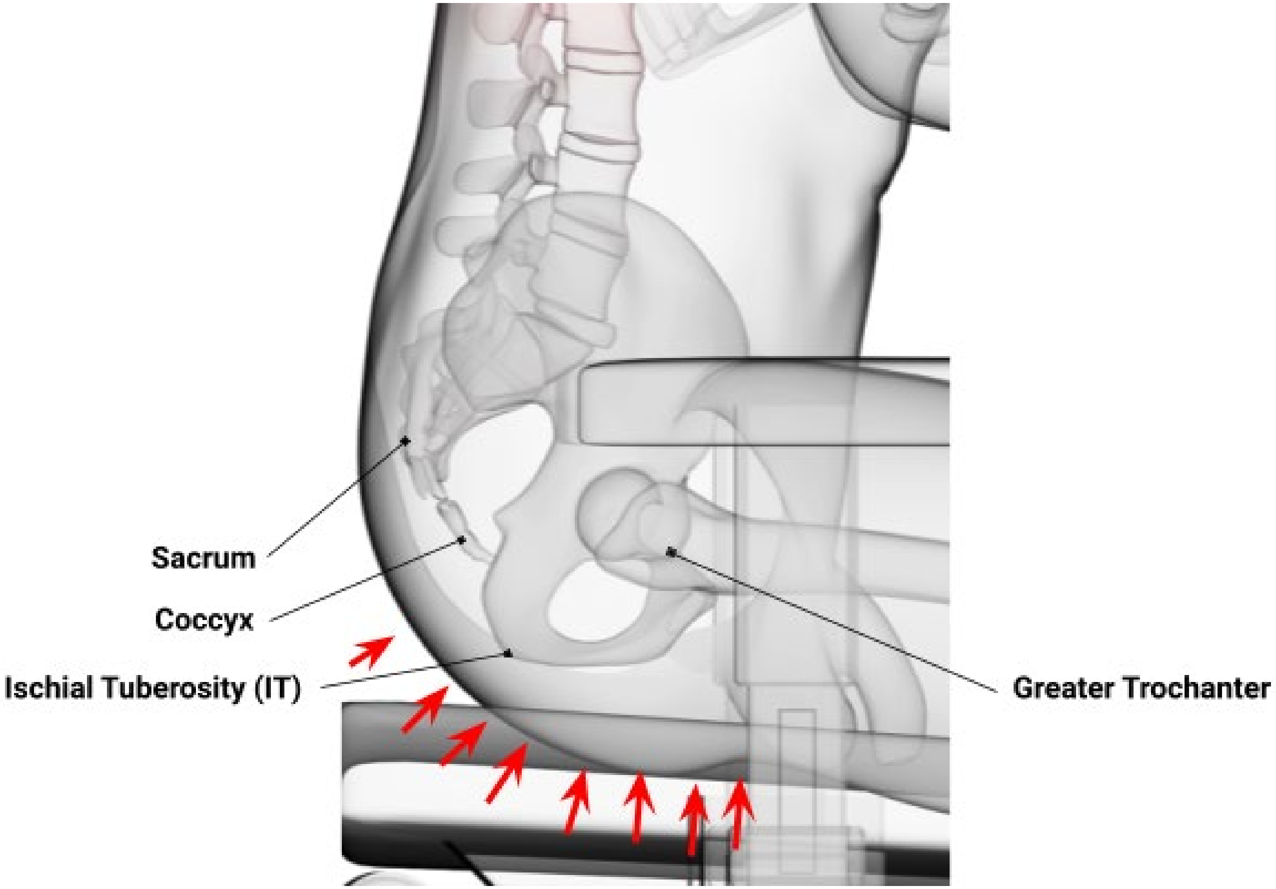
- 95% of those in the SCI (spinal cord injury) community are expected to have, or currently have, a PI

Sources: Kalogon - Inaugural Sitting and Seating Survey 2024
Kalogon - Orbiter White Paper

What is a pressure injury?

- Prolonged pressure on vessels supplying blood to tissues around pelvis, lower spine, and femur can lead to restricted blood flow, causing necrosis and the development of pressure injuries (PIs).

- Untreated pressure injuries can lead to extensive tissue damage, risking sepsis, exposure, and destruction of soft tissues, bone, nerves, and posing life-threatening complications for internal organs.



Explanations for the Etiology of Pressure Injuries

- 1. Soft tissue deformation leads to the reduction of perfusion, resulting in ischemia and all its consequences (e.g. reduced nutrients supply, accumulation of waste products, acidification). After off-loading the damaging effects may also be aggravated by a reperfusion injury.

- 2. Soft tissue deformation exceeding certain tolerance thresholds leads to direct deformation damage of cells through structural failure of the cytoskeleton and plasma membrane.

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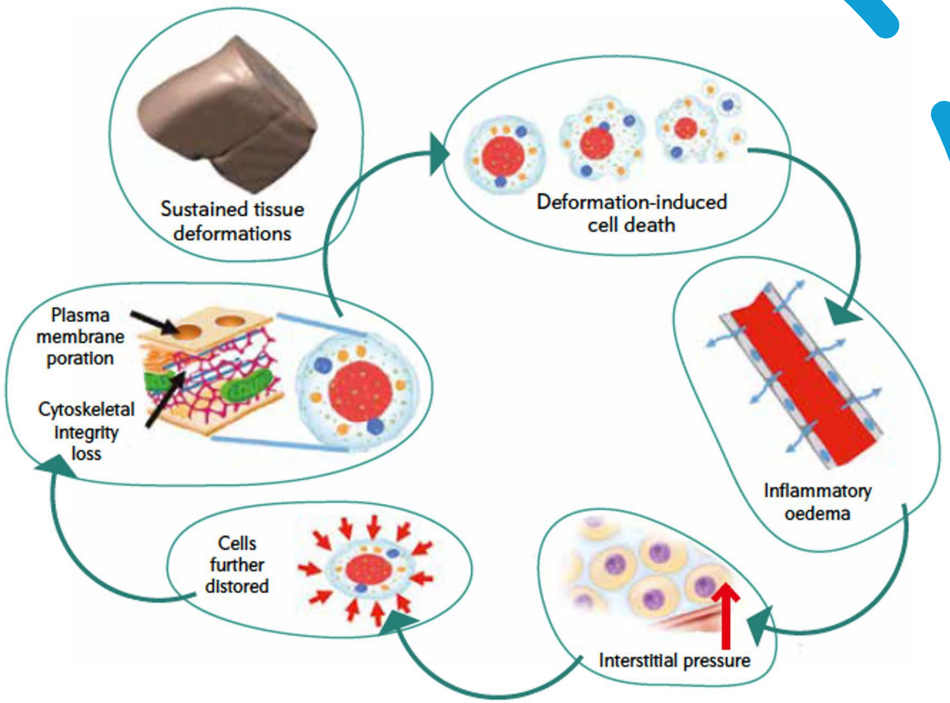
1. Blood Perfusion Explanation

- Past research reveals a consensus on the role of low blood perfusion, which leads to ischemic tissue damage and subsequent PI development.

- When seated, applied pressure compresses the vessels that supply blood, nutrients and oxygen to tissues around bony 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.



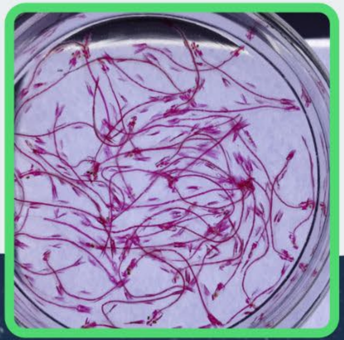
2. Cell Deformation Explanation

- Etiology of Pressure Ulcers in the Lens of the Vicious Cycle:
- The formation of pressure ulcers is a multifaceted process involving a sequence of damaging events.
- These events start with sustained mechanical loading causing direct cell deformation, followed by inflammatory edema, and culminating in ischemic damage.
- This progression forms a vicious cycle where each stage exacerbates the subsequent one.

The Vicious cycle of Tissue Deformation

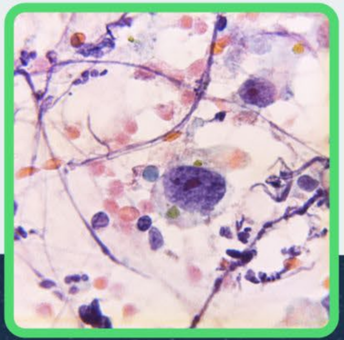
Vicious Cycle

01



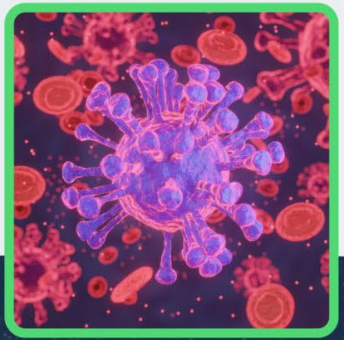
Direct Deformation: Continuous mechanical stress deforms cells, damaging their cytoskeleton and plasma membrane. This results in plasma membrane poration and abnormal cell function

02



Inflammatory Response: Deformation-induced cell damage triggers an inflammatory response. The release of chemokines attracts immune cells, causing local edema. This edema increases interstitial pressure, further distorting cells and accelerating tissue damage

03



Ischemic Damage: Persistent inflammation and increased interstitial pressure impair blood flow, leading to ischemic damage. This lack of adequate blood supply further contributes to tissue death and ulcer formation

- Cells in our body are constantly dying and being repaired. What makes cell death and repair different in this process?

- Pressure injuries develop when ***the rate of cell and tissue loss exceeds the rate of their renewal***, such as through cell growth, movement, and specialization

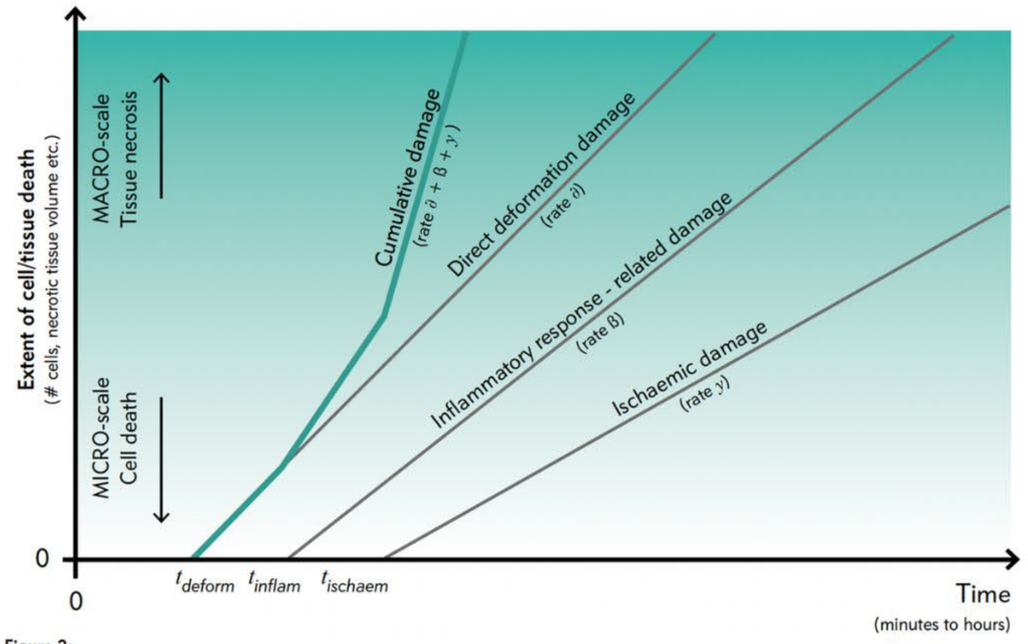


Figure 2:
There are three major contributors to cell and tissue death in pressure ulcers: direct deformation, inflammatory response, and ischaemia. (i) Direct deformation is the initial factor that begins to inflict damage at time point t_{deform} and progresses at a rate α. (ii) Inflammatory response-related damage occurs second at time point t_{inflam} and develops at a rate β. (iii) Finally, ischaemic damage is the last to appear at time point $t_{ischaem}$ and evolves at a rate γ. The combined contributions of these three factors at sequential time points explains the non-linear nature of the cumulative cell and tissue damage. This damage will accelerate from the micro-scale to the macro-scale and eventually exacerbate at a rate of α + β + γ.

Figure 2 from Gefen (2018)

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Stages of Pressure Injuries

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.

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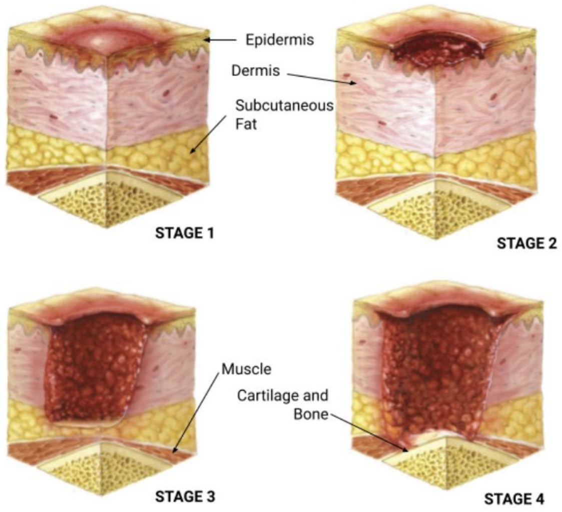

Preventing Pressure Injuries

• Pressure offloads are performed as the primary method for disrupting and redistributing applied pressures, allowing for blood flow to remain at normal and fairly constant levels.
• Common recommended offload techniques involve either a direct lift, leaning over to one side or leaning forward as if to reach for an object on the floor.

But we all know the challenges here:

- Remembering to do an offload.
- Physical capability to offload
- Ability to return to a seated position after an offload

Tilt

- Some models of powered or complex rehab chairs provide ‘tilt-in-space’ functions to help perform one’s offloads, allowing the user to tilt back and/or recline their wheelchair seat for a period of time, thus offloading at risk areas.

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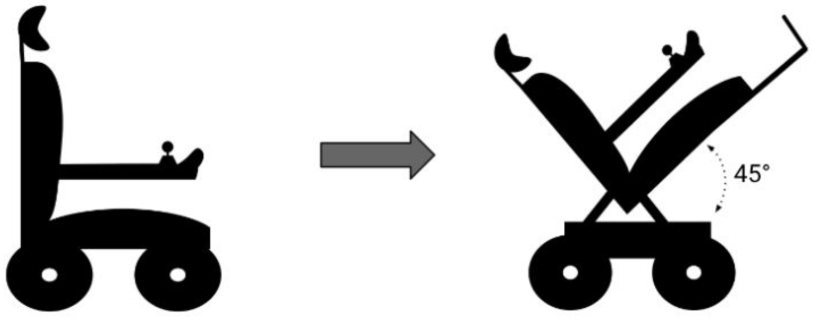

Current Solutions to manage Sitting Pressure: -Static Cushions

● **Distributive/Immersion/Envelopment**

- Distributes a user's applied pressure throughout the largest possible surface area through the use of a deformable medium
- Use air, foam, gel or a combination of some or all to disperse pressure

● **Offloading/Redistributing**

- Aims to remove pressures from at risk areas and redistributes it to surfaces more tolerant.
- Provide contouring around bony prominences in the pelvis to offload at risk areas

Current Solutions: Static Cushions

Air Cushions

- Generally effective at immersing a user's bony prominences
- Historically must be properly inflated using a manual pump to an inflation state that is critical to maintain but difficult to verify.
- Leaks and pressure changes result in the need for frequent clinical intervention to maintain a safe pressure
- Under or over-inflation limits the cushion's effectiveness

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Studies have aimed to find the best solution

- In a Stockton et al. (2002) study, 67.6% of 65 individuals using static air-flotation or gel cushions had previously experienced a pressure injury, and 24.6% had an existing pressure injury at the time of the survey.

- The study indicated that 48% of individuals surveyed while using static air-flotation cushions were currently experiencing pressure injuries, emphasizing that regardless of cushion type, both populations faced significant levels of pressure injury occurrence.

How can we maintain an Air Cell Based Cushion for maximum benefit using modern technology.

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Let’s be careful here of Tribal knowledge.

Air Management System (AMS)
controller that enhances most existing vertical air cell cushions to control and maintain pressure set by a clinician. Once the clinical pressure level is set by the clinician, Booster continuously monitors the cushion and automatically adjusts the level of air accordingly.

Ambient Sensing System (ASS)
continuously monitors and adjusts the cushion's air-inflation volume in response to various factors. These factors include changes in user posture, fluctuations in applied weight (such as when placing objects on one's lap during daily activities), gradual or sudden bodily weight changes, and even ambient conditions like altitude or weather (i.e. hot and cold weather) that can affect air pressure.

Leak Detection and Management
advanced leak detection and management abilities are designed to ensure user safety and expected cushion performance in the presence of changing ambient and user conditions. Booster continuously monitors air pressure within the cushion, and is capable of identifying leaks ranging from small punctures or shear-induced tears to substantial air loss situations.

Understanding the Dispersion Index

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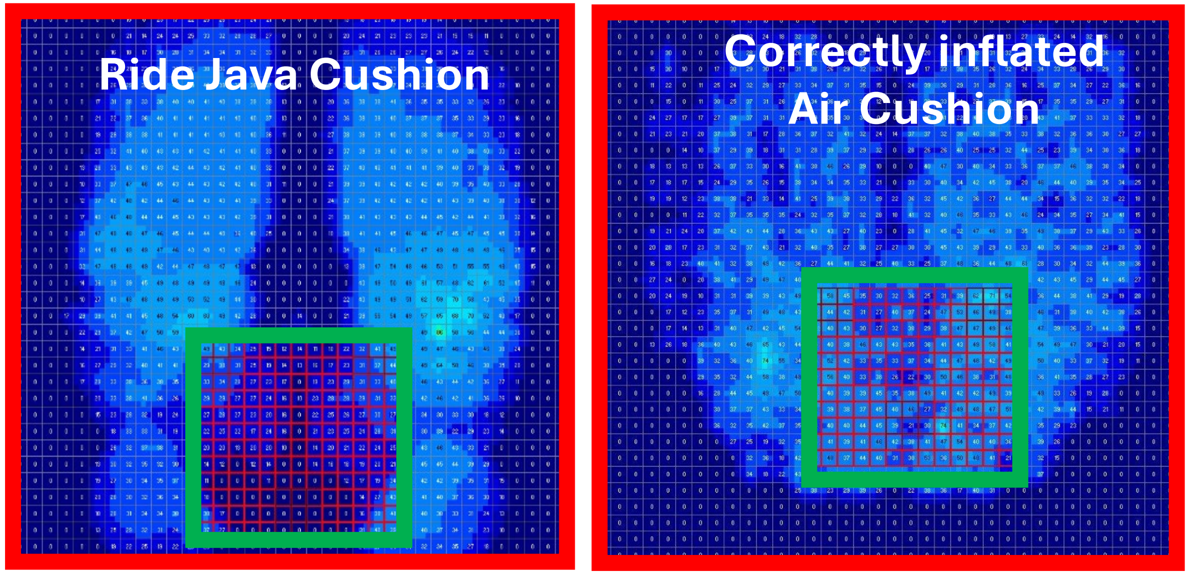
$$\text{Dispersion Index (DI)} = \frac{\text{sum of pressures in the region containing the ITs and sacrum (at risk)}}{\text{sum of pressures over the entire interface pressure mat}}$$

Lower DI means better protection of high risk areas!

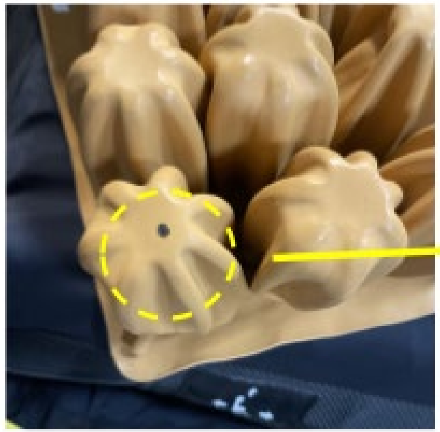


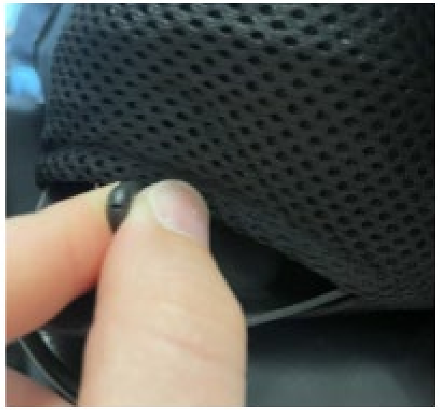
Results of Booster

1. ***Small Leak Tests***

Controlled leaks in test cushions and observed Booster's response.
These intentional tears mimicked shear-induced tears that naturally occur over time in air-based cushions due to users' transfers (See Figure 3).

Two primary test procedures were employed: a *Duration to Alarm test* to measure leak detection speed, and a *Leak Management Test* to assess long-term inflation maintenance in the presence of active leaks in the cushion.





Top: Star StabilAir with tear created per test procedure

Bottom: Roho with similarly created tear

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Results and Performance

- Booster's performance in these tests was noteworthy. In the Duration to Alarm tests, it consistently detected leaks far quicker than the one-hour benchmark, with an average detection time of approximately 7 minutes and 30 seconds (See Table 2).
- The Leak management tests demonstrated Booster's ability to maintain proper cushion inflation for a full hour, even with an active leak (See Table 2). This stood in sharp contrast to cushions without Booster, which bottomed out within 7 minutes under similar test conditions.

Test 1: Small Leak - Duration to Alarm				
Test Trial	**Duration to Alarm**	**Cushion Type**	**Cushion Size**	**Chair Type**
0001	7 min, 43 s	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC
0002	8 min, 58 s	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC
0003	7 min, 57 s	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Sling WC
0004	8 min, 27 s	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Sling WC
0005	10 min, 48 s	ROHO Hybrid Select*	Standard 18″ x 16″	Sling WC
0006	8 min, 22 s	ROHO Hybrid Select*	Standard 18″ x 16″	Sling WC
0007	8 min, 51s	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Power WC
0008	8 min, 10s	Star StabilAir	17.25″ x 17.25″ x 4″	Power WC
0009	2 min, 23s	Star StabilAir**	21″ x 21″ x 3″	Power WC
0010	12 min, 48s	Star StabilAir***	17.25″ x 17.25″ x 4″	Power WC
0011	1 min, 5s	Star StabilAir	17.25″ x 17.25″ x 4″	Power WC
0012	5 min, 57s	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC

Table 3: Data collected from the start of the test (T0) to the 1 hour mark (T 60), with a tester seated on a leaking cushion with Booster connected. *T0 = test start. T60 = 60 minutes* into the test.

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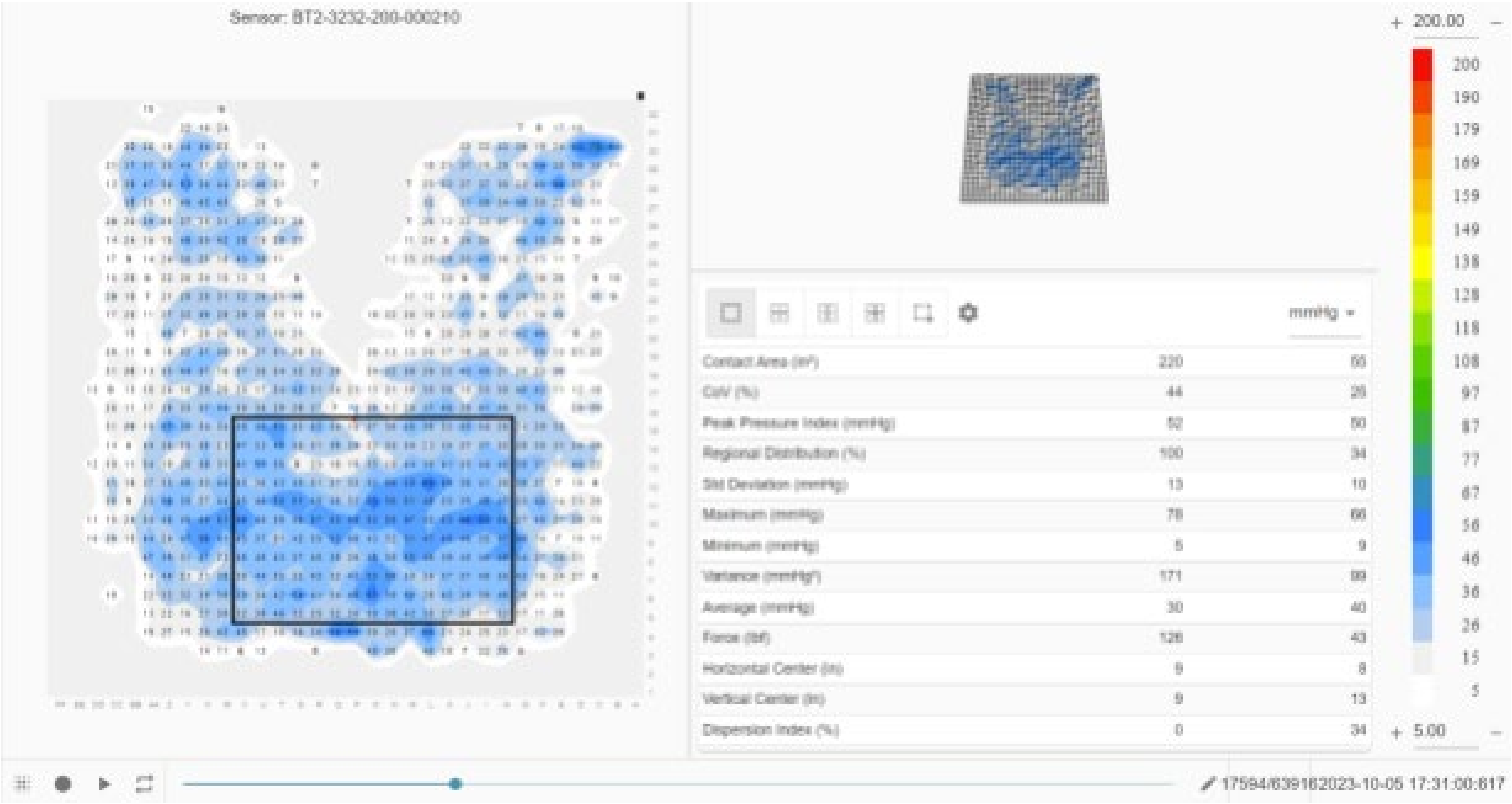
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Figure 5

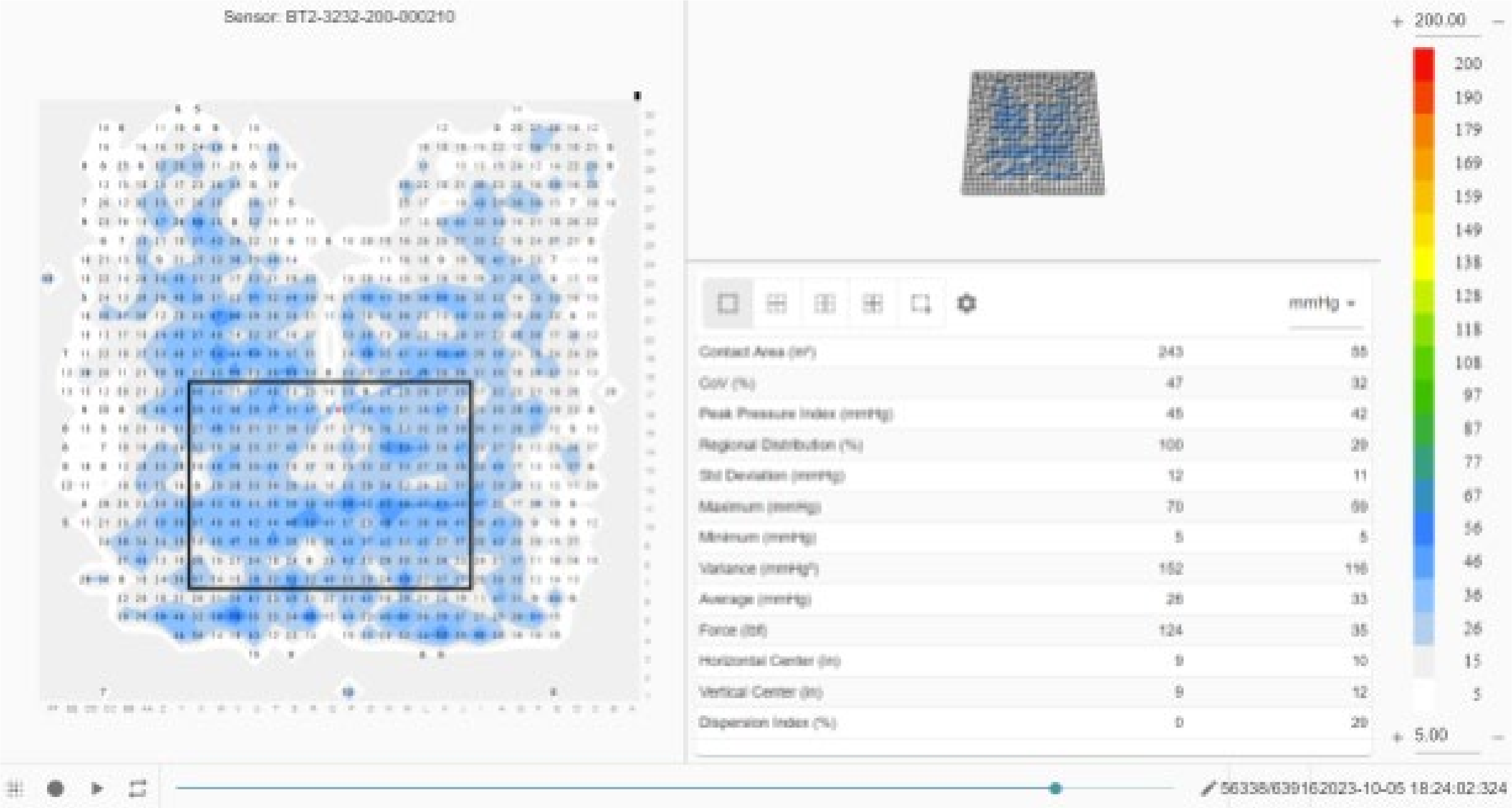

Figure 6: Pressure map data of Trial 1 at T0

overall pressure changes in the cushion over the test period were minimal, showing that Booster was able to maintain pressure map DI values at T60 or below T0 values

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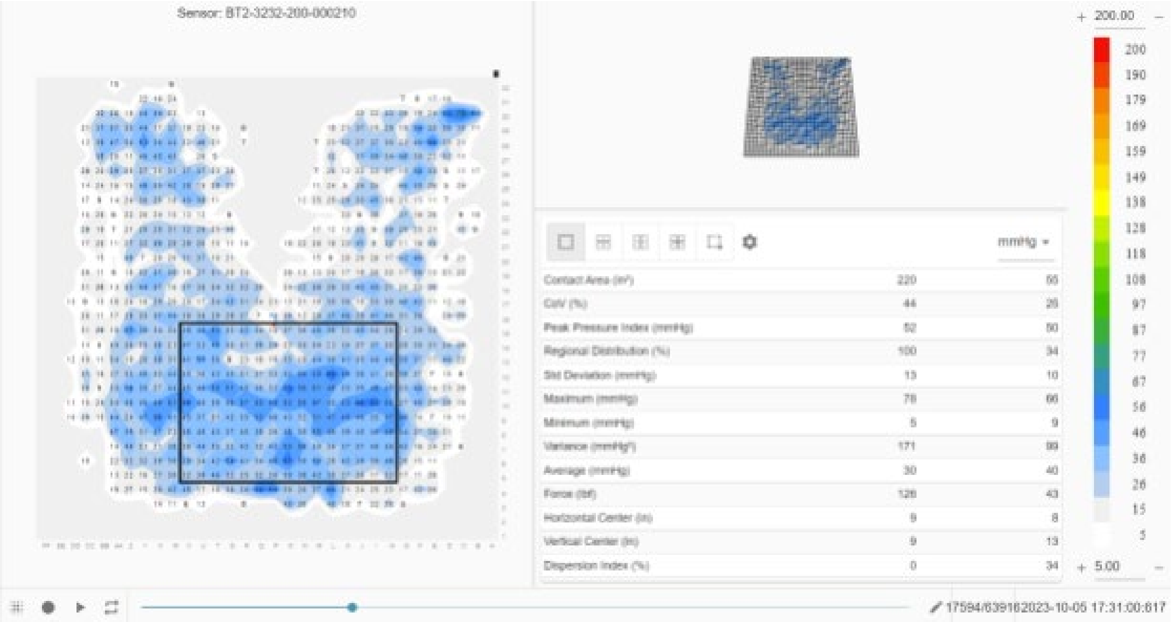

Figure 5

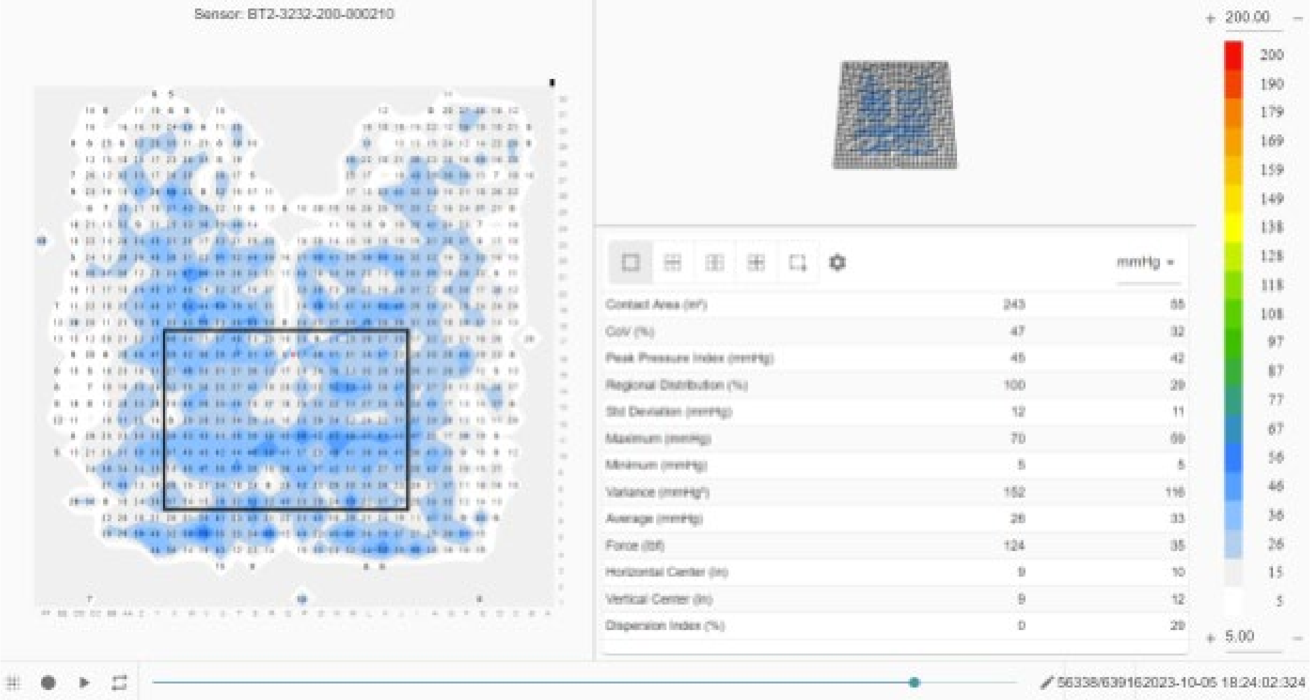

Figure 6

Test 2: Leak Management - Clinical Effects on Pressure Redistribution							
Test Trial	DI at T0	DI at T60	PPI at T0	PPI at T60	Cushion Type	Cushion Size	Chair Type
0001	34	29	50 mmHg	42 mmHg	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC
0002	34	33	55 mmHg	52 mmHg	Star StabilAir	17.25″ x 17.25″ x 4″	Power WC
0003	33	29	53 mmHg	95 mmHg	Star StabilAir	17.25″ x 17.25″ x 4″	Manual WC (Hard base)
0004	29	29	59 mmHg	95 mmHg	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Manual WC (Hard base)
0005	35	33	59 mmHg	84 mmHg	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Manual WC (Hard base)

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Table 3: Data collected comparing the DI and Peak Pressure Interfce from the start of the test (T0) to the 1 hour mark (T 60), with a tester seated on a leaking cushion with Booster connected. *T0 = test start. T60 = 60 minutes* into the test.

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2. Large Leak Tests

Large leak tests were designed to evaluate Booster's ability to detect and respond to significant air loss in cushions. A large leak was defined as air loss through a hole approximately 3 mm in diameter. This damage was simulated by attaching a manually adjustable relief valve to the cushion's fill port, allowing for controlled creation of a large leak.

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Test 3: Large Leak Test - Duration to Alarm

Test Trial	Duration to Alarm	Cushion Type	Cushion Size	Chair Type
0001	0 min, 34 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Power WC
0002*	0 min, 50 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Power WC
0003	0 min, 35 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Power WC
0004	0 min, 48 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Sling WC
0005	0 min, 47 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Sling WC
0006	0 min, 48 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Sling WC
0007	3 min, 55 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0008	3 min, 46 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0009	1 min, 09 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0010	5 min, 10 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0011	4 min, 47 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Sling WC
0012	3 min, 01 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Sling WC
0013	5 min, 14 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Sling WC
0014	0 min, 32 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0015	2 min, 42 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0016	0 min, 33 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0017	0 min, 50 s	Star, Standard	17.25″ x 17.25″ x 4″	Power WC
0018	0 min, 40 s	Star, Standard	17.25″ x 17.25″ x 4″	Power WC
0019	0 min, 34 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0020	0 min, 43 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC

Conclusions

- The large leak tests demonstrated Booster's remarkable efficiency in detecting substantial air loss in test cushions.
- By consistently alerting users to large leaks in under two minutes on average, Booster far exceeded the 10-minute detection requirement.
- This swift response time is crucial for preventing extended periods of inadequate cushion inflation and bottoming out, which could lead to discomfort or potential injury.
- While Booster is not designed to maintain cushion pressure in the presence of such large leaks, its rapid detection and alert system provide users with the timely information needed to address the issue promptly.
- These results suggest that Booster can significantly enhance the safety and reliability of air-cell cushions, offering users greater peace of mind and potentially reducing the risk of complications associated with sudden, substantial air loss.

3. Weight Change Management Tests

Methodology

The weight change management tests were designed to assess Booster's ability to maintain appropriate cushion inflation levels under varying applied weights.

Using an intact cushion, initial pressure mapping results were taken with the tester seated for 5 minutes, recording Distribution Index (DI), Peak Pressure Index (PPI), and pressure map images.

The tester then held incrementally heavier weights: 10 lbs, then 25 lbs, and finally 50 lbs total.

At each stage DI, PPI, pressure mapping images and notes indicating any audible indications of pumping or venting from the device were collected.

This test simulated scenarios such as a user placing a heavy backpack on their thighs or a user experiencing weight gain while using Booster.

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Peak Pressure Index as Weight Increases				
Trial	0 LBS	10 LBS 4.5kg	25 LBS 11.3kg	50 LBS 22.7kg
1	53	49	53	53
2	75	68	67	75
3	69	49	52	65
4	79	66	69	66
5	65	72	73	80
6 (Control - no unit)	55	74	85	91

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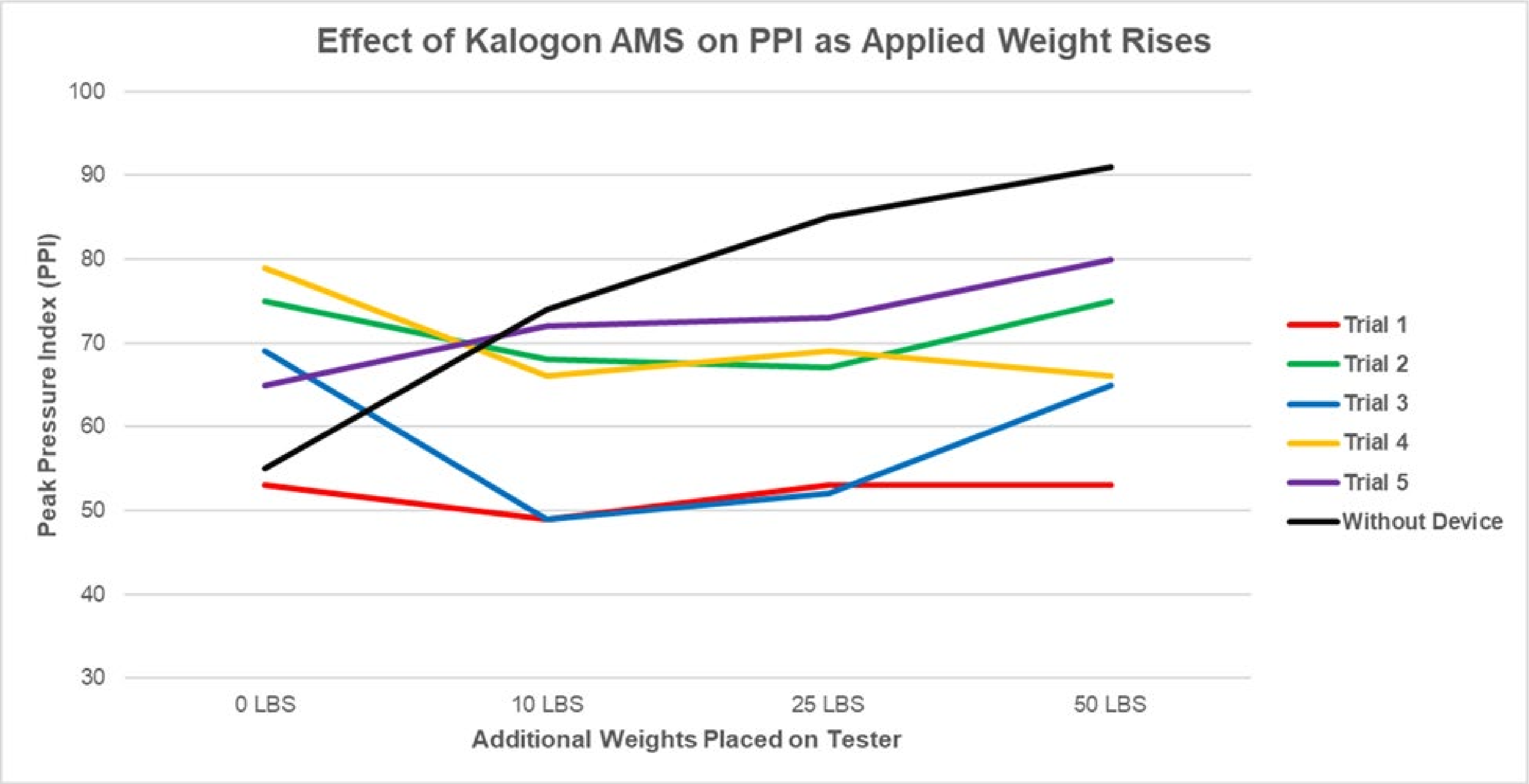
Effect of Kalogon AMS on Interface Pressure as User Weight Increases



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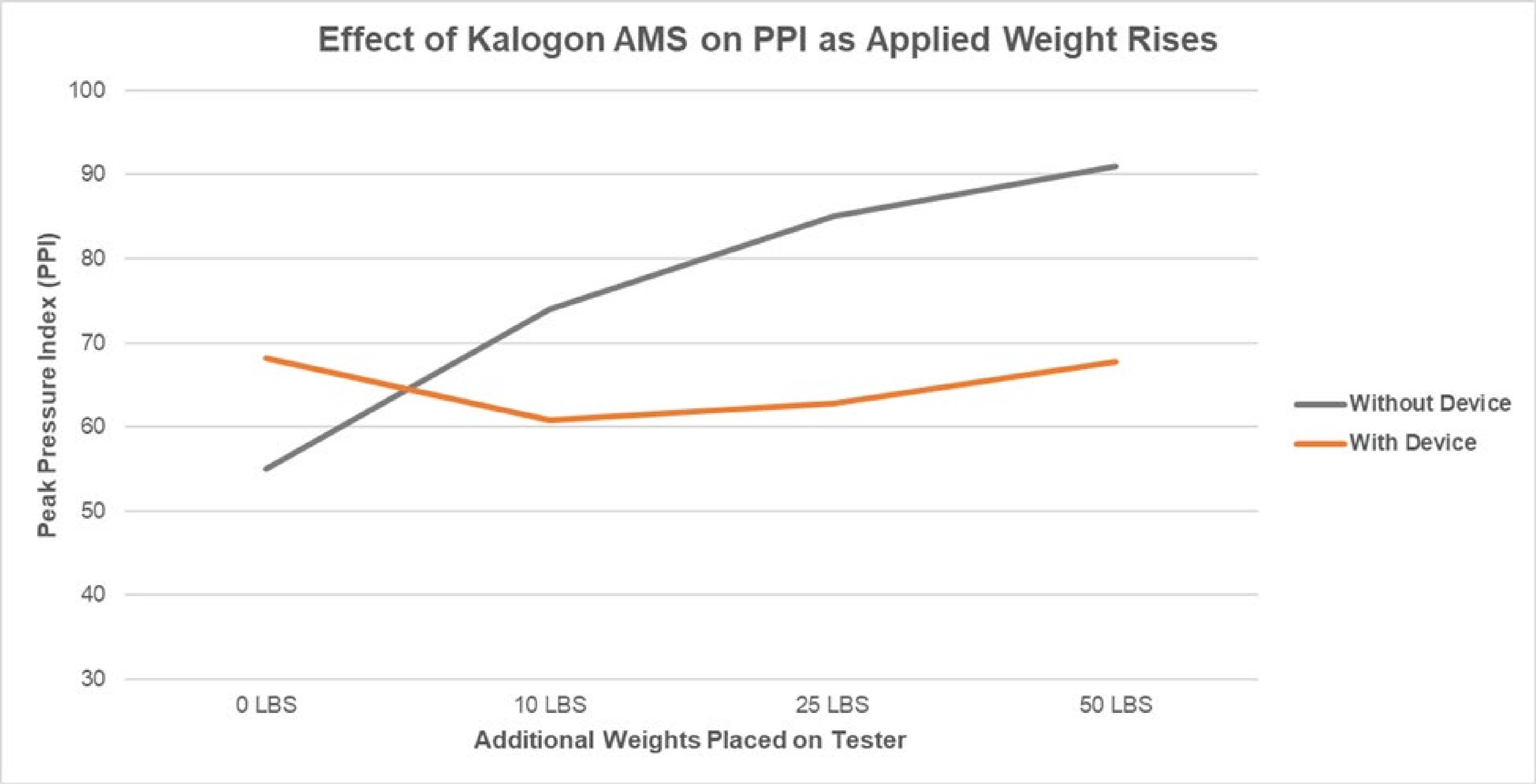
Average PPI Change with and without the device during weight management



Conclusion

- Pressure injuries remain a significant issue today, with high prevalence and substantial costs.
- Research suggests that a majority of these injuries are preventable, and prevention is more cost-effective than treatment (Ginningberg et al., 2018).
- Air-based cushions, along alternating air pressure cushions, offer effective options for reducing and preventing pressure injury risks.
- As such, Smart AI is a valuable technology that enhances the efficiency of single-chamber vertical air cell wheelchair cushions, monitoring correct inflation maintenance, providing leak detection and management, and offering a user-friendly way of adjusting inflation levels.

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