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Background

- **Orthostatic hypotension (OH)** - decrease in blood pressure $\geq 20\text{mmHg}/10\text{mmHg}$ in the first three minutes after standing or head up tilt-table testing¹
 - 6% of US population (~20M patients)²
- **Symptoms** – lightheadedness, dizziness, weakness, syncope, confusion, nausea
- **Causes** – damage to center and/or peripheral sites in baroreceptor efferent pathway
 - Drug-induced, depletion of total or effective intravascular volume, primary neurogenic, secondary neurogenic
 - Conditions such as Parkinson's, diabetes, multiple system atrophy, multiple sclerosis, and syringomyelia, among others³
- **Risks** – falls, stroke, cardiovascular diseases
- 2.5 times greater risk of recurrent falls for individuals with OH compared to elderly counterparts without OH
- Seen in 52% of advanced and older patients with Parkinson's disease

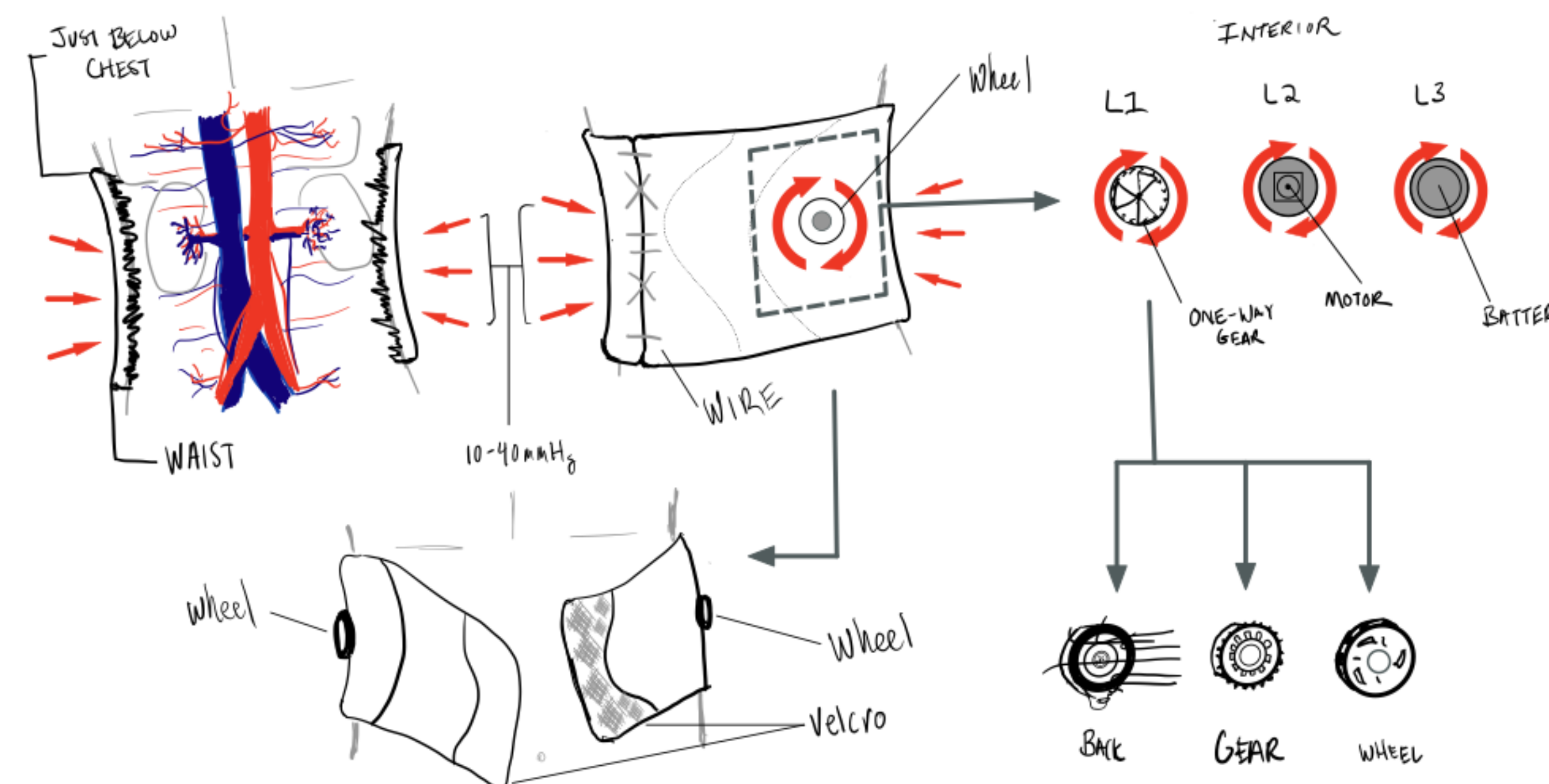
Orthostatic Hypotension (OH) Treatment

- Standard of care for OH treatment: four steps⁴
 1. Assess and adjust pre-existing medications
 2. Non-pharmacologic approaches
 - Blood volume repletion
 - Diet (smaller meals, less sodium)
 - Physical conditioning
 - Avoiding increased body temperature
 - Compression garments
 3. Single-agent pharmacologic approach
 4. Combined pharmacologic treatment
- Most non-pharmacologic approaches have shown limited efficacy⁴
- Knee-high compression garments ineffective⁴
- Low patient compliance with existing abdominal compression garments⁴
 - Require fitting, difficult to put on, and uncomfortable especially in hot climates

Device Specifications

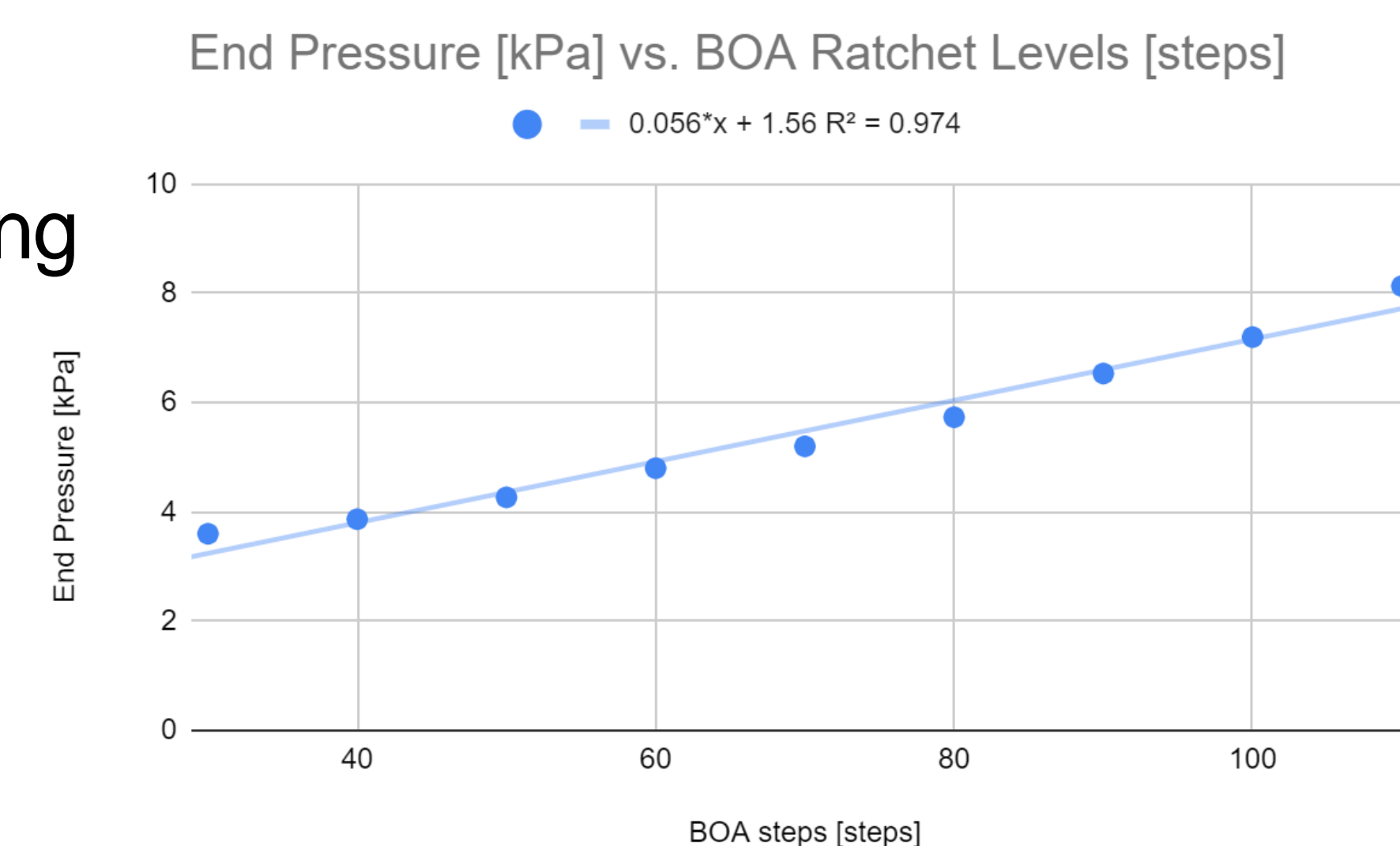
Active Compression Elastic Abdominal Binder

- Nylon coated wires span abdomen with mesh-like structure in rear
- Gear tightening system for secure fit and quick adjustments
- Force-sensing resistor placed on interior of binder around abdomen
- Motor systems connected to mobile device and using wearables data for activation parameters
- Binder size: 68-114 cm
- Response time <10 s to apply compression within 1.3-5.3 kPa
- Lightweight, weighing <1 lb



Verification testing



- Prototype constructed using Boa® Fit System Technology
- Compression measured using mannequin
- Achieves reliable, safe compression



References

- [1] Fanciulli A, Goebel G, Metzler B, et al. Elastic Abdominal Binders Attenuate Orthostatic Hypotension in Parkinson's Disease. *Movement Disorders Clinical Practice*. 2015;3(2):156-160. doi:10.1002/mdc3.12270. [2] Orthostatic hypotension: MedlinePlus Genetics. *MedlinePlus*. 18 August 2020. medlineplus.gov/genetics/condition/orthostatic-hypotension/. Accessed December 6, 2020. [3] Freeman R, Abuzinadah AR, Gibbons C, Jones P, Miglis MG, Sinn DI. Orthostatic Hypotension. *Journal of the American College of Cardiology*. 2018;72(11):1294-1309. doi:10.1016/j.jacc.2018.05.079. [4] Gibbons CH, Schmidt P, Biaggioni I, Frazier-Mills C, Freeman R, Isaacson S, Karabin B, Kuritzky L, Lew M, Low P, Mehdirdad A, Raj SR, Vernino S, Kaufmann H. The recommendations of a consensus panel for the screening, diagnosis, and treatment of neurogenic orthostatic hypotension and associated supine hypertension. *J Neurol*. 2017;264:1567-1582. doi:10.1007/s00415-016-8375-x. [5] François C, Biaggioni I, Shihao C, Ogbonnaya A, Shih H, Farrelly E, Ziemann A, and Duhig A. 2017. Fall-related healthcare use and costs in neurogenic orthostatic hypotension with Parkinson's disease. *Journal of Medical Economics*, 20(5):525-532. [6] Global Orthostatic Hypotension Drugs Market: Industry Type, Share, Trends and Forecast 2019-2025. *Zion Market Research*. 2019. www.zionmarketresearch.com/report/orthostatic-hypotension-drugs-market. [7] Okamoto L, Diedrich A, Baudenbacher F, et al. Efficacy of Servo-Controlled Splanchnic Venous Compression in the Treatment of Orthostatic Hypotension. *Hypertension*. 2016;68(2):418-426. 10.1161/HYPERTENSIONAHA.116.07199.

Advantages Versus Existing Solutions

	Effectiveness	Ease of use
Compression stockings 	Not designed for OH, minimal improvement in symptoms and in BP	Difficult to put on, uncomfortable
Abdominal wraps 	Not designed for OH, improvements in symptoms when worn correctly	Typically requires assistance from a second person to put on, uncomfortable
Our device: active compression abdominal binder	Optimized to provide compression when needed to increase standing BP and prevent symptoms	Designed to be easy to slip on and simple to adjust to comfortable tightness

Market Validation

- Consequences of untreated OH:⁵
 - More fall-related ED visits, hospitalizations, and outpatient visits and services
- Estimated cost savings $> \$10\text{k}$ per year per patient
 - Fall-related cost savings of successful OH treatment using the drug Droxidopa: $\$14.5\text{k}$ ⁵
 - OH drug market in 2015: $\$560.9\text{M}$, expected to increase to $\$978.5\text{M}$ by 2025⁶
 - Patients with both Parkinson's Disease and OH have over $\$10\text{k}$ more costs per year than Parkinson's patients without OH⁵

Data from François et al. (2017) ⁵	Parkinson's (n = 17,421)	Parkinson's & OH (n = 281)
Fall-related ED visits	10%	18%
Hospitalizations	3%	7%
Outpatient services	10%	15%
Total All-Cause Costs	\$20,910	\$31,260