

Scoliosis

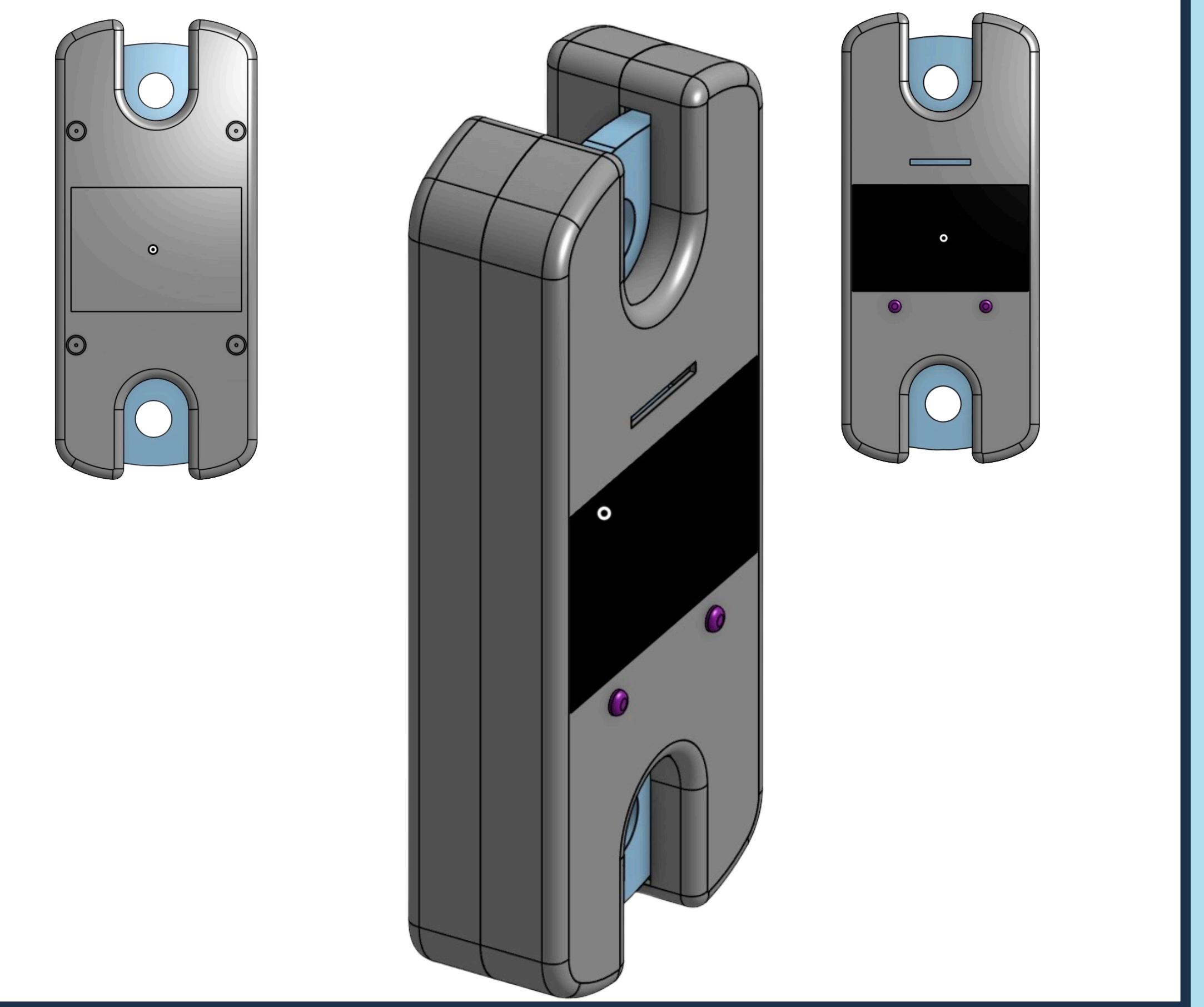
- Scoliosis is a condition where the spine curves sideways, typically in an "S" or "C" shape.
- Affects about 2–3% of the population, most commonly adolescents.
- Severe scoliosis is usually defined as a spinal curve greater than 40–50 degrees.
- Can cause visible deformity, back pain, limited mobility, and in some cases, breathing or cardiac issues.
- Severe scoliosis often requires preoperative treatment, such as halo gravity traction, to gradually reduce spinal curvature and improve surgical outcomes.



SPINEALIGN™

Real-Time Monitoring Device for Halo Gravity Traction

Ayse Baysal, Ari Jindal, Lucas Kiukawa, Davi Souza, Varsha Venkatapathy

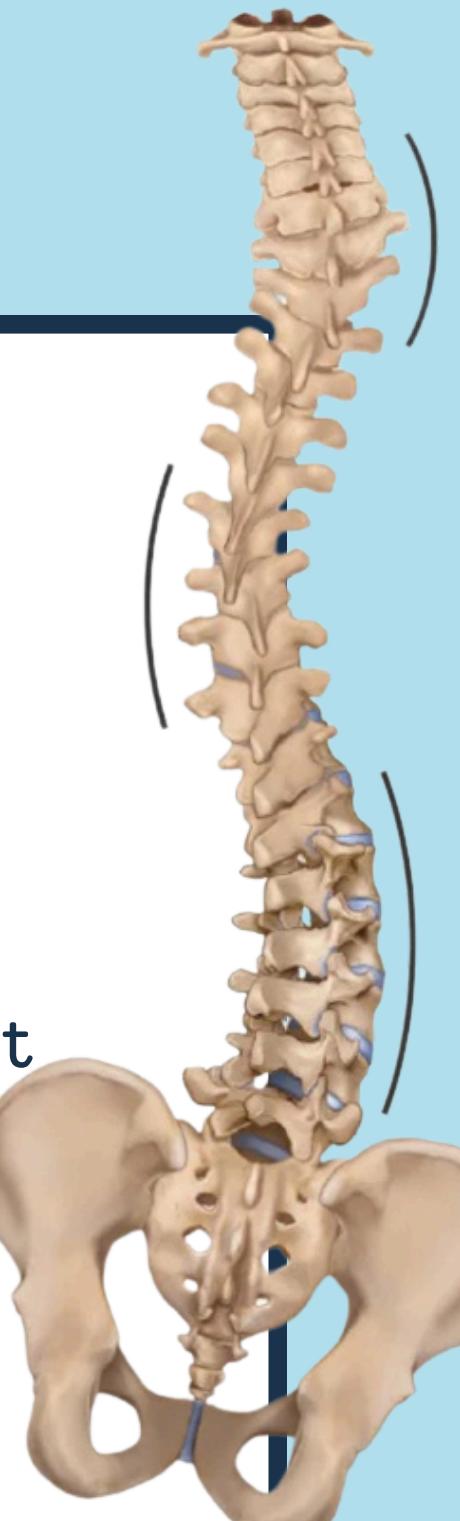


Halo Gravity Traction

- Halo Gravity Traction (HGT) is a preoperative treatment used to gradually straighten the spine in patients with severe scoliosis before surgery.
- It involves a halo ring fixed to the skull and connected to weights via a pulley system, applying gentle, continuous traction over time.
- Patients typically use HGT for several weeks to a few months, depending on the severity of the curve and how they respond.
- Doctors usually check in weekly to monitor progress, adjust the load, and make sure the spine is responding appropriately.
- If patients remove weight or don't apply the full prescribed load—often due to discomfort, limited mobility, or lack of supervision—the treatment may appear less effective.
- As a result, doctors might increase the load unnecessarily, thinking the traction isn't working, when in reality the issue is inconsistent use rather than inadequate force.

Our Solution

- Our device continuously monitors and records traction load in real time during halo gravity traction therapy.
- It stores up to a week's worth of data on an SD card, allowing doctors to review usage patterns on a computer during check-ins.
- Equipped with long-lasting batteries, the device is designed to last the entire treatment period without frequent recharging.
- It easily attaches between the halo ring and the traction cable, with quick reattachment to different setups like the walker, wheelchair, or bed.
- A built-in LCD screen displays the real-time load, allowing doctors and caregivers to verify that the correct weight is being applied.
- By providing accurate usage data, the device helps doctors avoid overcorrecting or prolonging treatment due to unrecognized underuse.



THERE IS A NEED FOR A HALO GRAVITY TRACTION SYSTEM WITH INTEGRATED REAL-TIME, CONTINUOUS LOAD MONITORING TO ENSURE PRECISE TREATMENT ADJUSTMENTS BASED ON APPLIED FORCES AND USAGE DURATION.

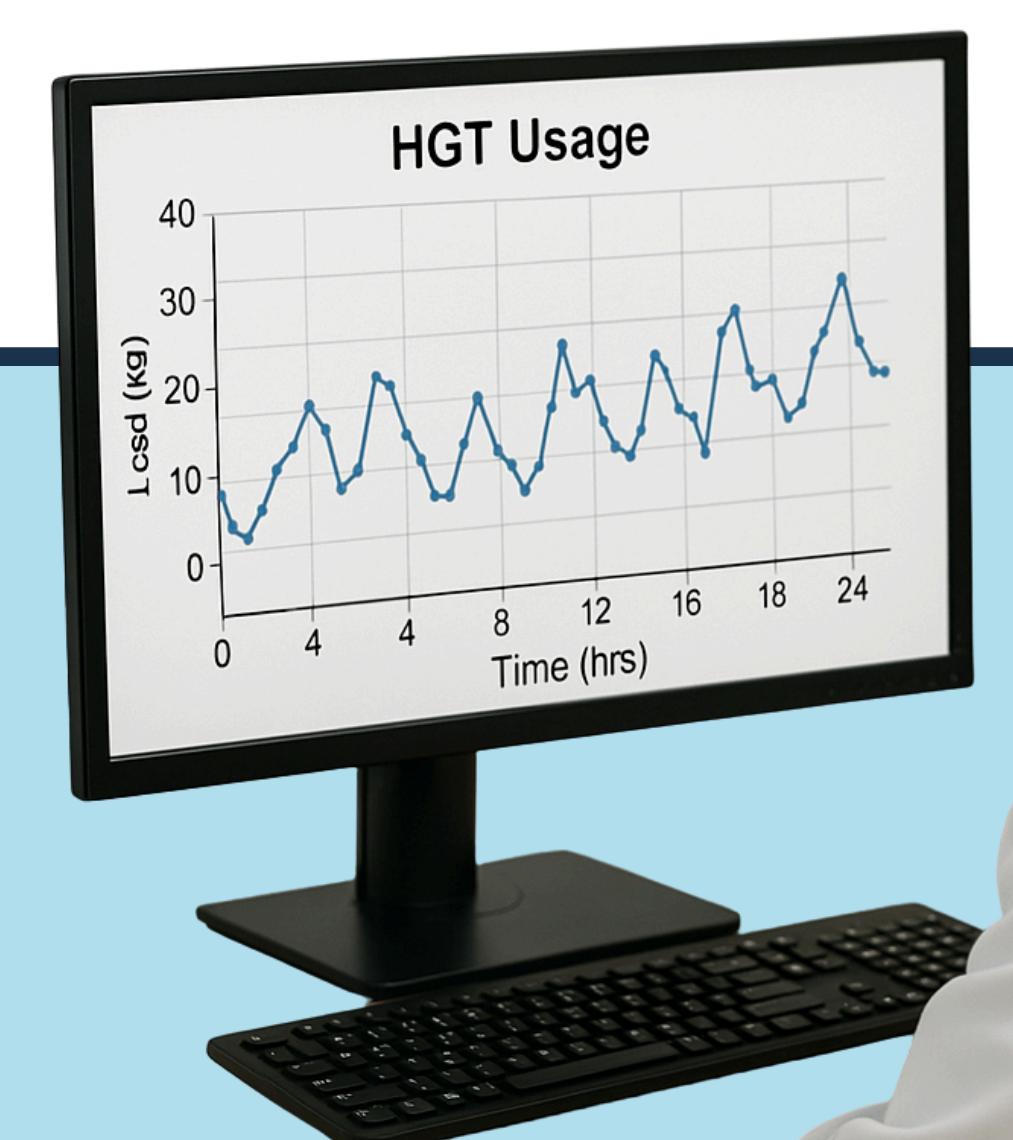
Testing



- Drop tests verified the durability of the device casing.
- Electrical and communication checks ensured stable power, wiring, and data flow between components.
- Calibration tests confirmed accurate zeroing.
- Noise and environmental testing assessed signal stability under vibration.
- SD card validation ensured reliable data storage and retrieval.
- Tested across a range of loads, with system output matching applied weight within 95% accuracy.

Market/Reimbursement/Regulation

- Target users include pediatric spine centers, orthopedic surgeons, caregivers of the patient, and hospital staff managing halo traction.
- Fills a market gap by tracking real-time traction load and usage outside the clinic.
- Helps reduce complications and treatment time by enabling data-driven traction adjustments.
- Likely qualifies as a Class I or II device under FDA guidelines; potential for 510(k) exemption or clearance.
- May not have direct CPT reimbursement but supports bundled care models and improves outcomes in reimbursed procedures.
- Designed for easy integration with existing traction setups across hospital environments.



Acknowledgements

We would like to extend a special thanks to Dr. Lloyd Hey, Dr. Kenneth Donnelly, Dr. Devin Hubbard, Joseph Sharp, Dr. Akif Baysal, Charles McCall, and Dr. Glenn Walters for their invaluable guidance, feedback, and support throughout the development of this project.

References:

SpineHealth Foundation. (n.d.). Scoliosis: Information you can use. Retrieved March 27, 2025, from <https://spinehealth.org/article/scoliosis-information-you-can-use/>

Boston Children's Hospital. (n.d.). Halo gravity traction. Retrieved March 27, 2025, from <https://www.childrenshospital.org/treatments/halo-gravity-traction>

University of South Alabama. (2023, January 9). Halo gravity traction treatment helps young scoliosis patients. Retrieved March 27, 2025, from <https://www.southalabama.edu/departments/publicrelations/pressreleases/010923halo.html>