

FlexForward

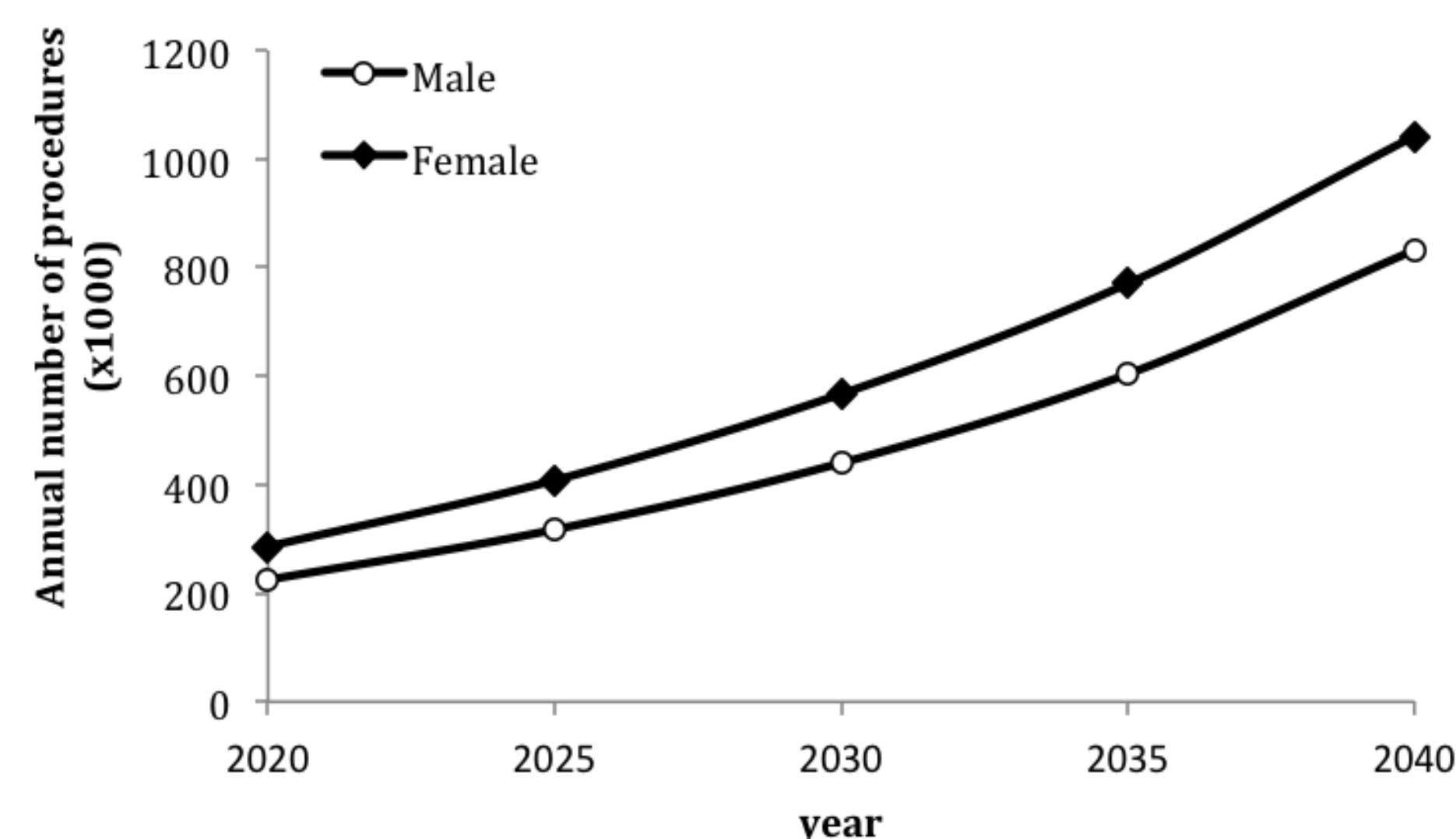
Aidan Hoffman, John Goebel, Josh Stansell, Kabir Dewan, Virginie Ruest

Lampe Joint Department
of Biomedical Engineering

Redefining At-Home Range of Motion Recovery

BACKGROUND

Total Knee Replacement (TKR) is the surgical replacement of injured or worn-out knees with artificial parts and is becoming increasingly common, especially in individuals who are over 45 years old, obese, and have knee osteoarthritis.^{1,2}



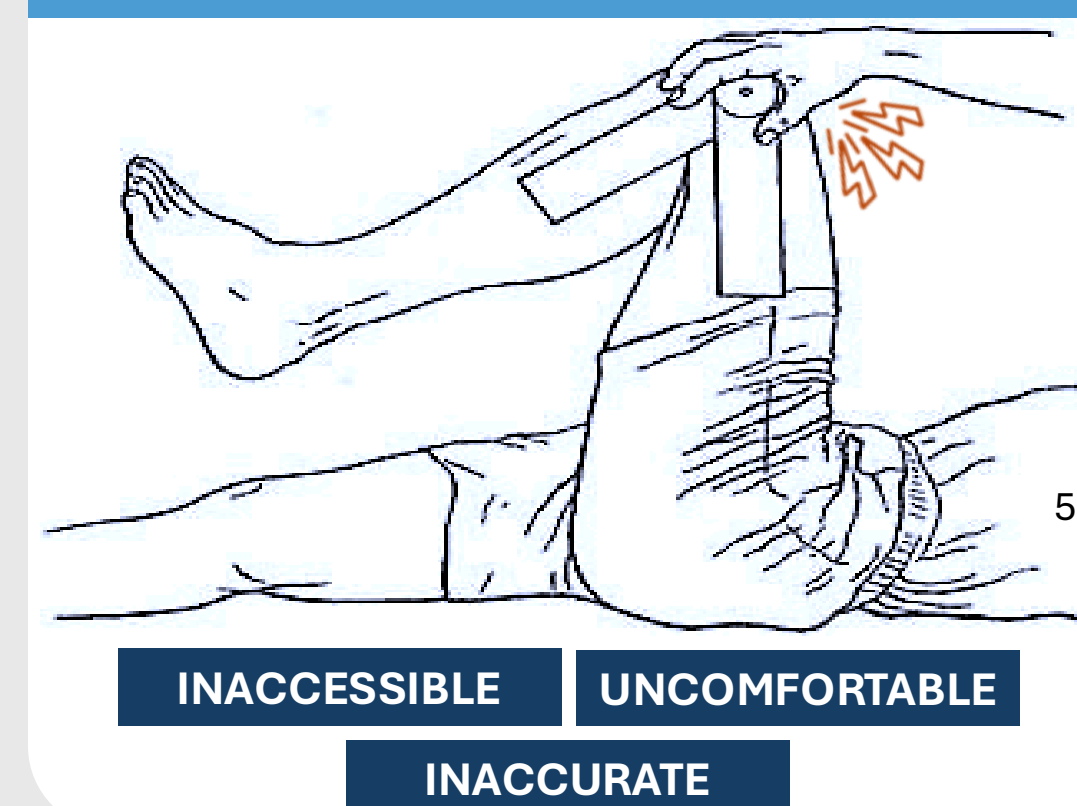
In 2024, approximately **790,000 TKRs** were performed in the United States.^{3,4} This number is expected to continue to grow annually as our population ages.

After TKR surgery, patients attend weekly physical therapy sessions to improve their knee joint mobility. However, they often **miss their physical therapist's prescribed range-of-motion (ROM) milestones** because they lack a user-friendly tool that provides at-home, real-time feedback of their knee joint angle.



Goal: Address the confidence of total knee replacement patients during at-home physical therapy to improve range of motion recovery

EXISTING SOLUTIONS

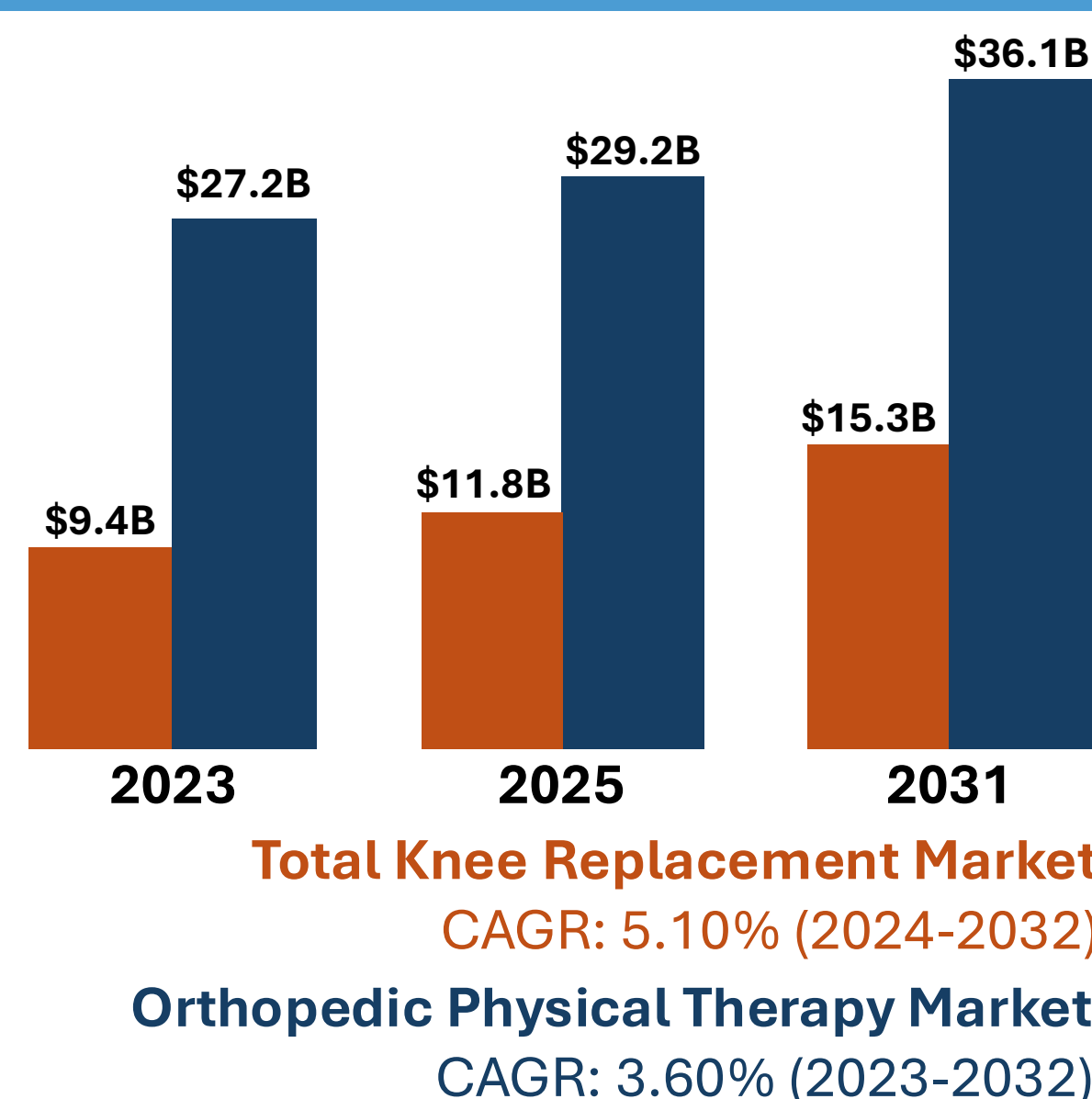


In the clinic, physical therapists use **mechanical goniometers** to assess ROM, but they are impractical for at-home use. The lateral angle reading and replicable positioning of the goniometer proves challenging for older populations. This leads to using the existing device incorrectly or opting to use no device, thus causing **inaccurate judgement of joint angles** and **missed ROM milestones** upon returning to weekly physical therapy.

MARKET

One of the driving forces for market growth is the **increasing prevalence of orthopedic diseases** and associated risk factors. Compounded with an **aging population** and a desire for **less invasive surgical procedures**, the demand for knee replacement surgery is on the rise.^{6,7}

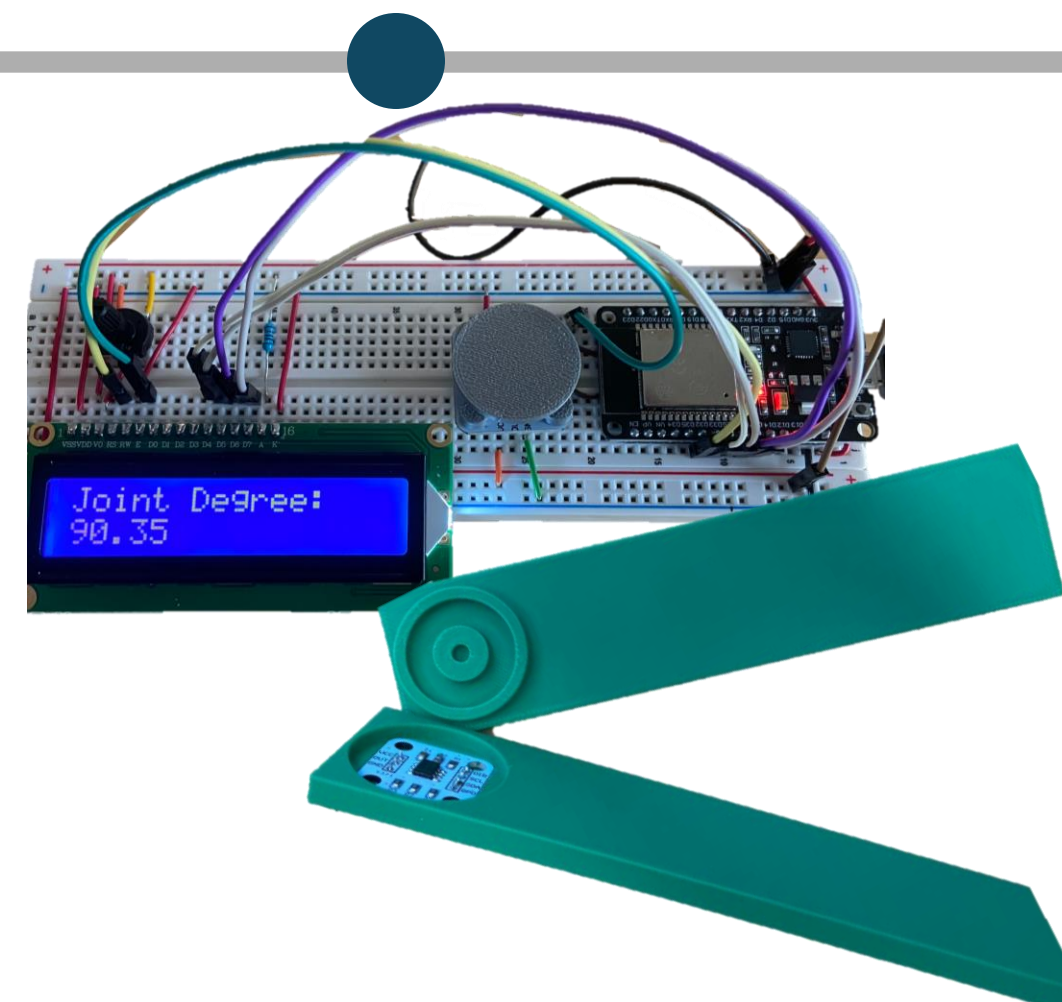
1 in 5 patients are **not satisfied** with the results of their TKR surgery, thus contributing to growth in the orthopedic physical therapy sector.⁷



This project could not have been possible without the help of the following advisors:
Dr. Thomas Marusko, Dr. Devin Hubbard, Dr. Glenn Walters, Dr. Bob Dennis, and Joseph Sharp

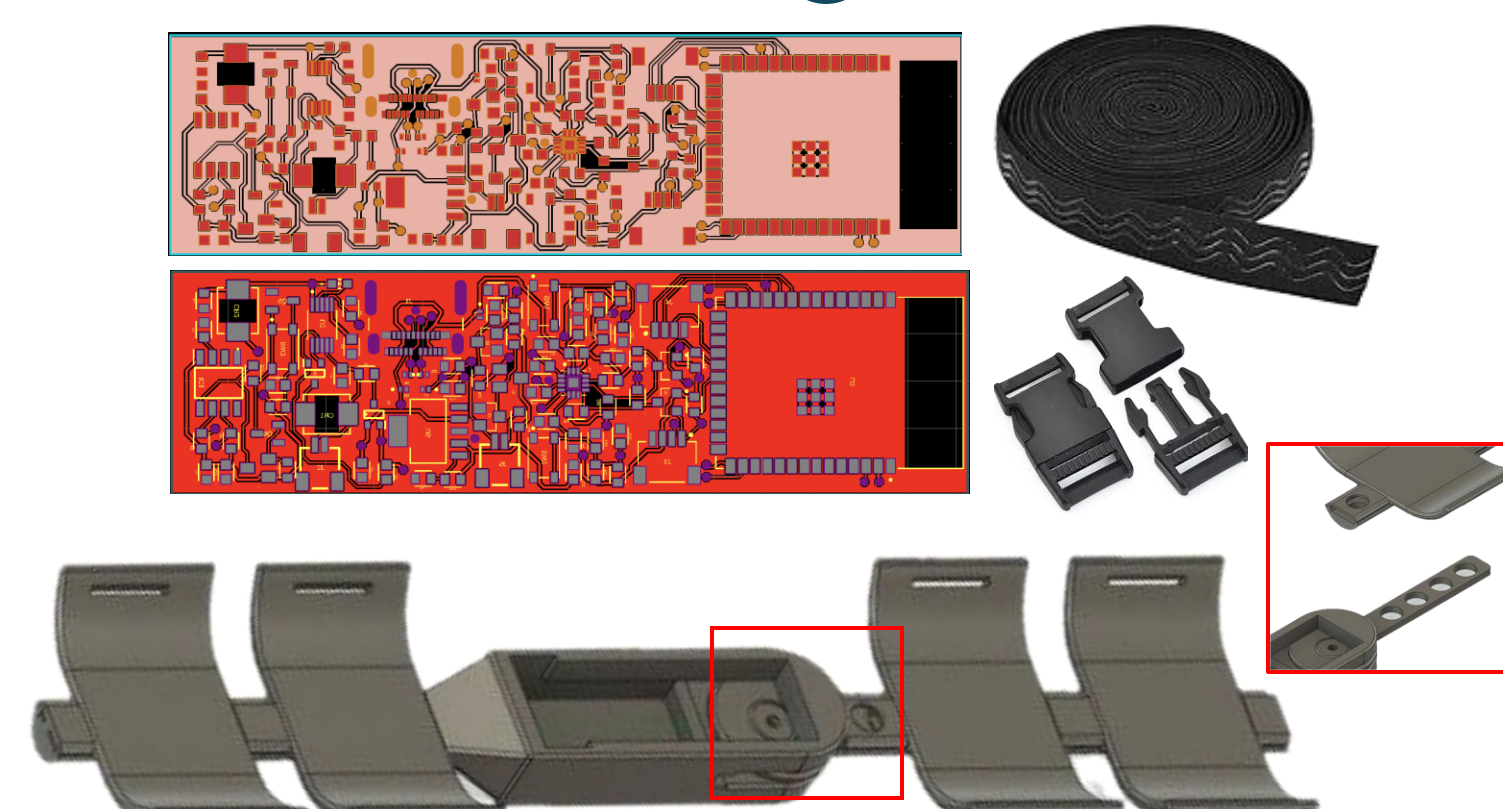
OUR PROGRESS

Proof-of-Concept



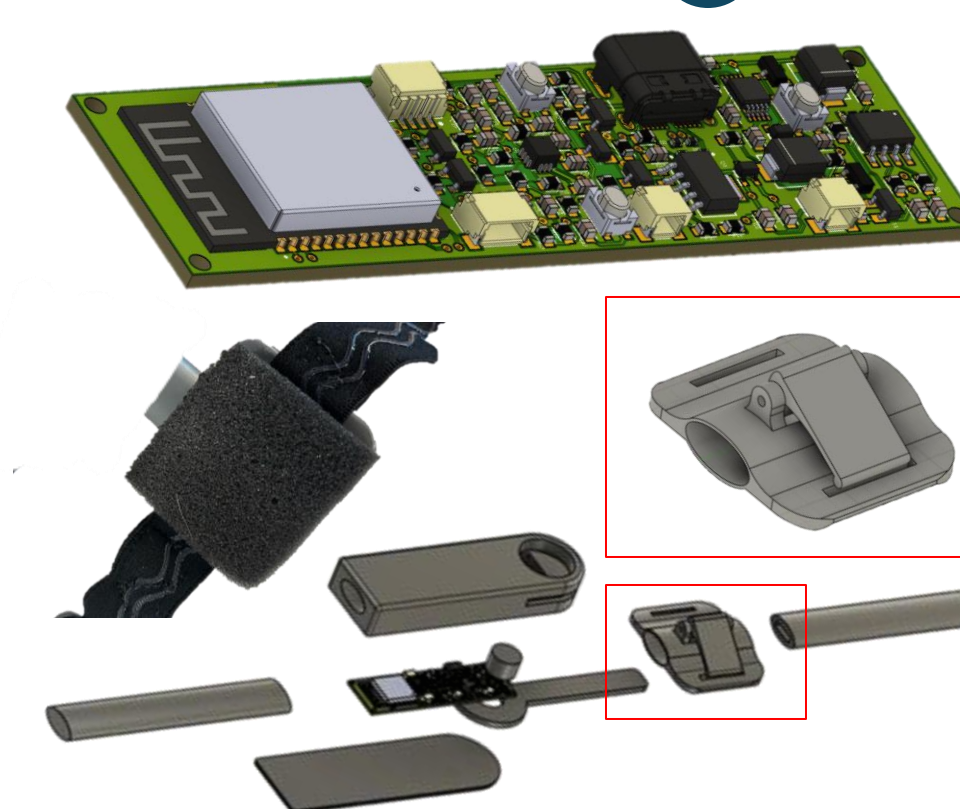
- No Attachment Mechanism
- Bulky Electronics & Exposed Wiring
- Not User-Friendly

Alpha Prototype



- Developing Attachment Mechanism: Elastic Straps & Buckles
- PCB Footprint Iterations & Testing
- Contoured, Adjustable Pad & Pin Design

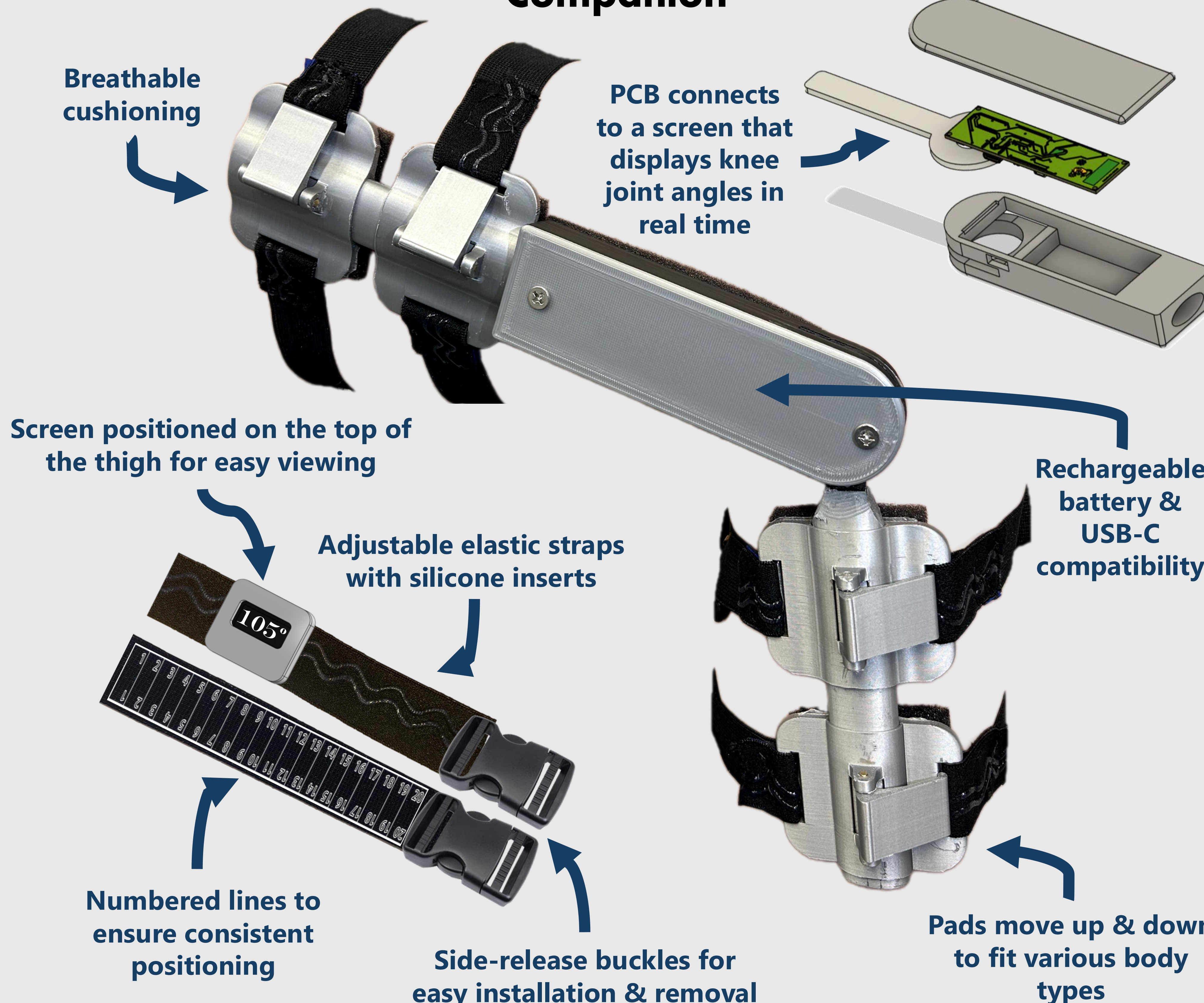
Beta Prototype



- Finalized Attachment Mechanism: Reinforced Straps & Buckles
- Working, Rechargeable Electronics
- Latching Pads & Removable Cushioning

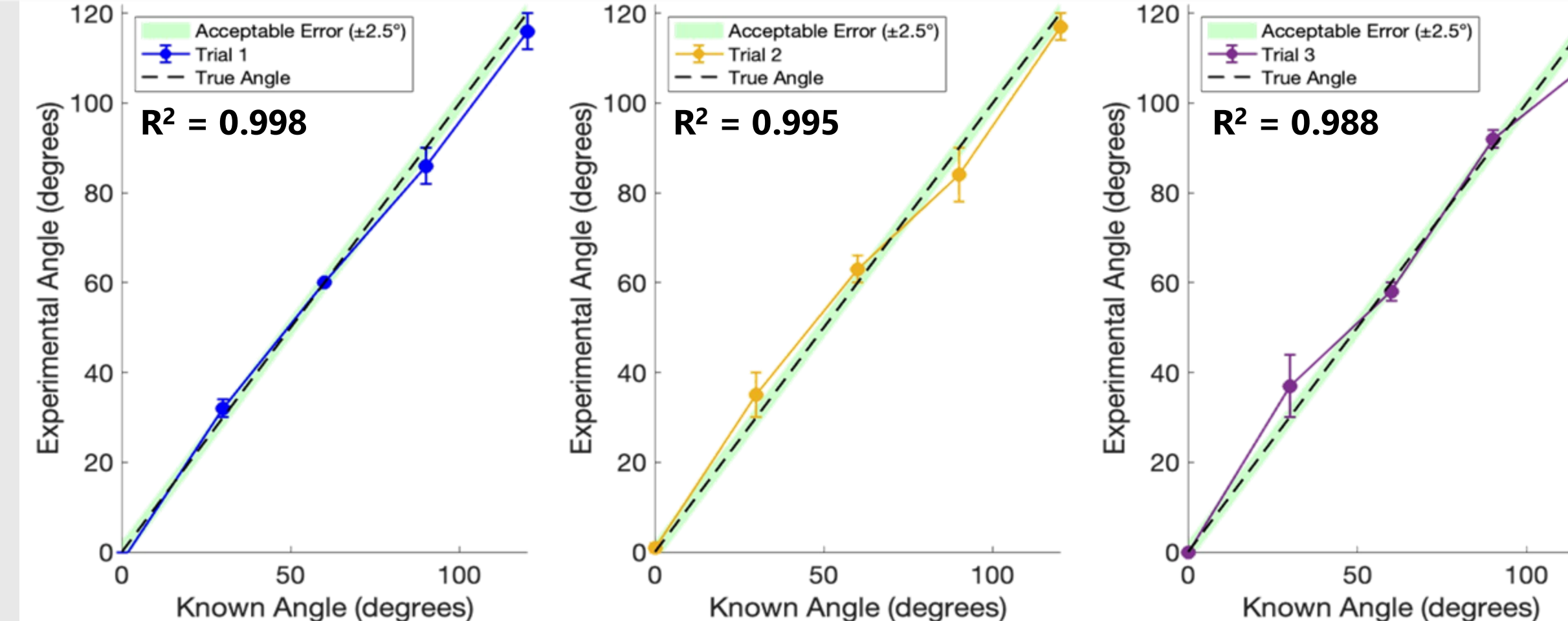
BEND-i

Your At-Home Knee Angle Monitoring Companion



TESTING

COMPARISON OF BEND-i's MEASURED ANGLES TO TRUE ANGLES

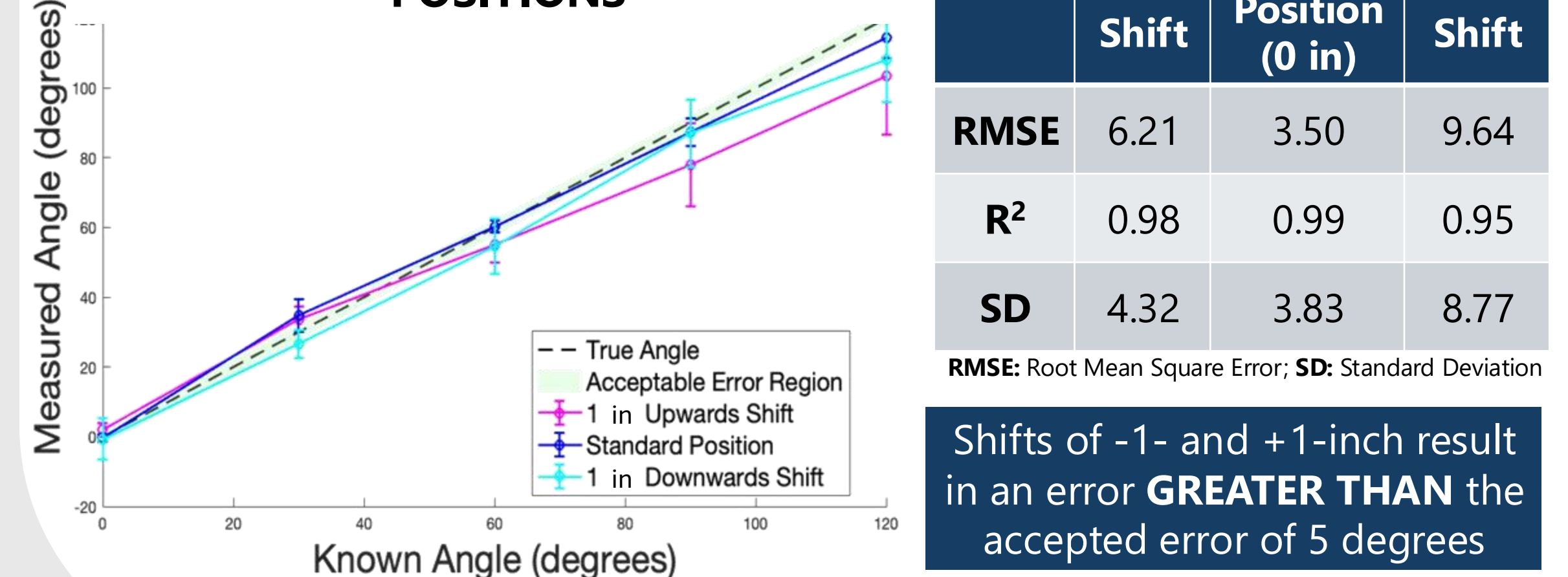


Goal: Comparing the accuracy of Bend-i to the gold-standard goniometer

Calibration Offset:
2.9 ± 1.8 degrees

Average Root Mean Square Error:
4.1 ± 1.1 degrees

BEND-i's ACCURACY AT DIFFERENT POSITIONS



REGULATION & REIMBURSEMENT

Regulation Number: 888.1500

BEND-i falls under the **Class II medical device** category due to its electronic components. However, it is **exempt from 510(k) premarket notification** requirements.^{9,10}

Since BEND-i is included in the take-home surgical package, its cost is **not reimbursed separately**. Instead, it is considered part of the overall surgical care and **covered under Current Procedural Terminology (CPT)** guidelines as a post-surgical supply within the global surgical package. If used for range of motion measurement, it may be billed under **CPT 95851**.¹¹



MANUFACTURING PLAN

Components	Strategy
Encasement	<ul style="list-style-type: none">- Made of aluminum 5052- Injection molding of encasement, pads, and clamps- Purchasing hollow aluminum bars from McMaster-Carr- Waterjet cutting for the encasement of the rotary encoder
Electrical	<ul style="list-style-type: none">- Mass manufacturing with JLPCB
Straps	<ul style="list-style-type: none">- Purchasing the straps from Pacific Trimming

REFERENCES

- [1] F. H. Nham, I. Patel, and A. K. Zalikka, "Epidemiology of primary and revision total knee arthroplasty: Analysis of demographics, comorbidities, and outcomes from the national inpatient sample," *Arthroplasty*, vol. 5, p. 18, 2023. [Online]. Available: <https://doi.org/10.1186/s4236-023-00175-6>
- [2] S. Williams, M. Wolford, and A. Berovitz, "Hospitalization for total knee replacement among inpatients aged 45 and over United States, 2000-2010," *Products - Data Briefs*, no. 211, Aug. 2015. [Online]. Available: <https://www.cdc.gov/nchs/products/databriefs/db210.htm>. Accessed: Mar. 22, 2025.
- [3] American College of Rheumatology, "Joint replacement surgery," *Rheumatology.org*. [Online]. Available: <https://rheumatology.org/patients/joint-replacement-surgery>
- [4] ACR Abstracts, "Rates of total joint replacement utilization in the U.S.: Future projections to 2020-2040 using the national inpatient sample." [Online]. Available: <https://acrabstracts.org/abstract/rates-of-total-joint-replacement-utilization-in-the-u-s-future-projections-to-2020-2040-using-the-national-inpatient-sample/>
- [5] ResearchGate, "Goniometer position to measure leg flexion and extension movements." [Online]. Available: <https://www.researchgate.net/publication/244810358/figure/fig/2/AS:95090159473665@1603737978233/Goniometer-position-to-measure-leg-flexion-and-extension-movements-1.jpg>
- [6] Vision Research Reports, "U.S. physical therapy services market." [Online]. Available: <https://www.visionresearchreports.com/us-physical-therapy-services-market/39988>
- [7] Zion Market Research, "Total knee replacement market." [Online]. Available: <https://www.zionmarketresearch.com/news/total-knee-replacement-market>
- [8] Knee Replacements UK, "Outcomes & Results: Knee replacement surgery." [Online]. Available: <https://kneereplacements.co.uk/outcomes-results-knee-replacement-surgery/>
- [9] U.S. Government, "Electronic Code of Federal Regulations: 21 CFR 888.1500." eCFR.gov. [Online]. Available: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-888/section-888.1500>
- [10] U.S. Food and Drug Administration (FDA), "Product classification: NDI." [Online]. Available: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NKI>
- [11] American Academy of Professional Coders (AAPC), "CPT code 95851." [Online]. Available: <https://www.aapc.com/codes/cpt-codes/95851>