# HeelLink: A Smart Adaptive Insole for Idiopathic Toe Walking Rehabilitation

*An early-stage smart corrective insole concept for conservative management of pediatric idiopathic toe walking*

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## INTRODUCTION

### Clinical problem

- Idiopathic toe walking (ITW) persists in a subset of children after age 5 and may require conservative intervention.
- Common options such as physical therapy, AFOs, and serial casting can improve motion or gait but often show variable real-world adherence.
- This project targeted a low-profile insole that can support gait retraining during normal daily activity.

## DEVICE CONCEPT

### Closed-loop corrective workflow

Heel & forefoot sensors → Onboard controller detects ITW → Micropump changes heel drop → Pressure sensor enforces limit → BLE app shows trends and wear time

### Passive geometric correction

- Toe-walking is detected when forefoot force dominates and heel contact is absent or below threshold.
- A clinician-set pneumatic bladder raises heel drop within a 4–16 mm adjustment range.
- The design is intended to fit inside normal school shoes and log heel-strike %, wear time, and trend data.

### Key design distinctions

- Passive correction rather than punitive vibration alerts.
- Remote clinician adjustment with closed-loop gait data collection.
- Low-profile architecture intended for everyday pediatric footwear.

## DESIGN REQUIREMENTS (CTQS)

- Retain ≥85% of heel-cup depth under worst-case loading.
- Maintain safety factor ≥2.0 for the structural body material.
- Provide clinician-controlled heel-drop adjustment from 4–16 mm.
- Use long-term skin-contact materials with a credible biocompatibility pathway.
- Keep the device low profile enough to fit normal shoes.

## PROJECT SCOPE

In Scope:
- A functional proof-of-concept prototype was fabricated.
- Engineering Feasibility
- Material Selection

Out of Scope:
- No gait study, long-term wear study, or human-subject testing was performed in this phase.

## METHODS

### Development approach

- Literature review → needs statements → CTQ definition → concept selection → CAD development.
- Evaluation combined static FEA with a ISO 10993-1 biocompatibility review.

### Worst-case combined zone loading

| Heel | Arch | Forefoot | Toes |
|---|---|---|---|
| 450 N | 150 N | 550 N | 180 N |

## MATERIAL COMPARISON

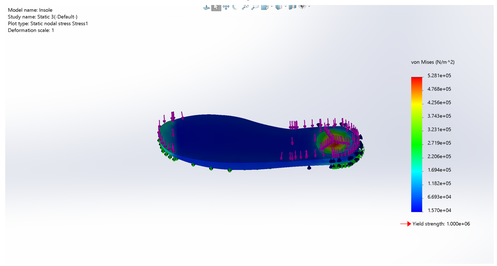
| Property | EVA foam | SORTA-Clear 40 |
|---|---|---|
| Elastic modulus | 8.0 MPa | 0.621 MPa |
| Poisson's ratio | 0.35 | 0.47 |
| Density | 200 kg/m³ | 1080 kg/m³ |
| Strength metric | Compressive strength 0.8 MPa | Tensile strength 5.52 MPa |
| Intended role | Structural insole body | Pneumatic bladder |

## PROTOTYPE OUTCOME

- A proof-of-concept prototype demonstrated low-profile geometry and internal component packaging feasibility.
- Prototype development in this phase focused on build feasibility rather than performance validation.

## FEA RESULTS

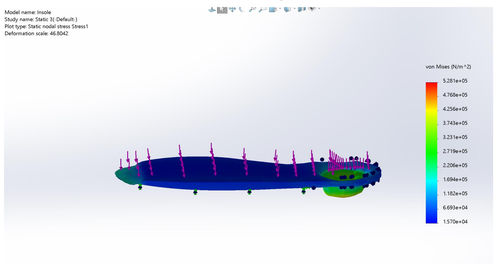
**EVA foam — selected structural body**




**PASSED**

- Heel-cup geometry was preserved under the same worst-case loading scenario.
- Peak stress remained below the compressive limit; safety factor was >2.0.
- Chosen as the structural insole body material.

**SORTA-Clear 40 — not suitable as body material**




**FAILED**

- Max URES = 4.886 mm at the heel versus a designed heel-cup depth of ~4 mm.
- Failure mode was geometric collapse, not material fracture.
- Retained as the pneumatic bladder material because compliance is useful in that role.

## RESULTS AT A GLANCE

**EVA foam**
Passed structural evaluation
Selected for insole body

**SORTA-Clear 40**
Failed as body material
Retained for bladder

**Biocompatibility**
Both materials suitable for intended roles

Desktop review supported cytotoxicity / sensitization / irritation rationale under ISO 10993-1; formal lot-level testing would still be required before clinical use.

## CONCLUSIONS AND NEXT STEPS

### Conclusions

- This project established an early-stage design basis for a smart corrective insole for ITW.
- FEA supported the material architecture of EVA foam for the body and SORTA-Clear 40 for the air bladder.
- The prototype showed build feasibility, but clinical performance remains untested.

### Future work

- Exact-material prototype fabrication and pneumatic bench testing.
- Fatigue testing, firmware/app development, and BLE integration.
- Clinical feasibility work with pediatric stakeholders.

## SELECT REFERENCES

[1] Bauer et al. JAAOS, 2022
[5] Caserta et al. Cochrane Review, 2019
[7] Pollind et al. Biomed Sci Instrum, 2019
[14] Verdejo & Mills, J Biomech, 2004
[17] ISO 10993-1:2018
Full list in report

## SCAN FOR FULL REPORT

Methods, complete references, and supporting detail

## ACKNOWLEDGEMENTS

Thank you to Dr. Mikkel C. Jarman and Dr. Thurmon Lockhart for project guidance and support through the MS Applied Project program at the Ira A. Fulton Schools of Engineering, Arizona State University.

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