Diabetic foot: Devices for Long Term Prevention

(Beyond traditional orthotic prescriptions)

Max Hurwitz, DO

9th Annual Comprehensive Wound Care Symposium

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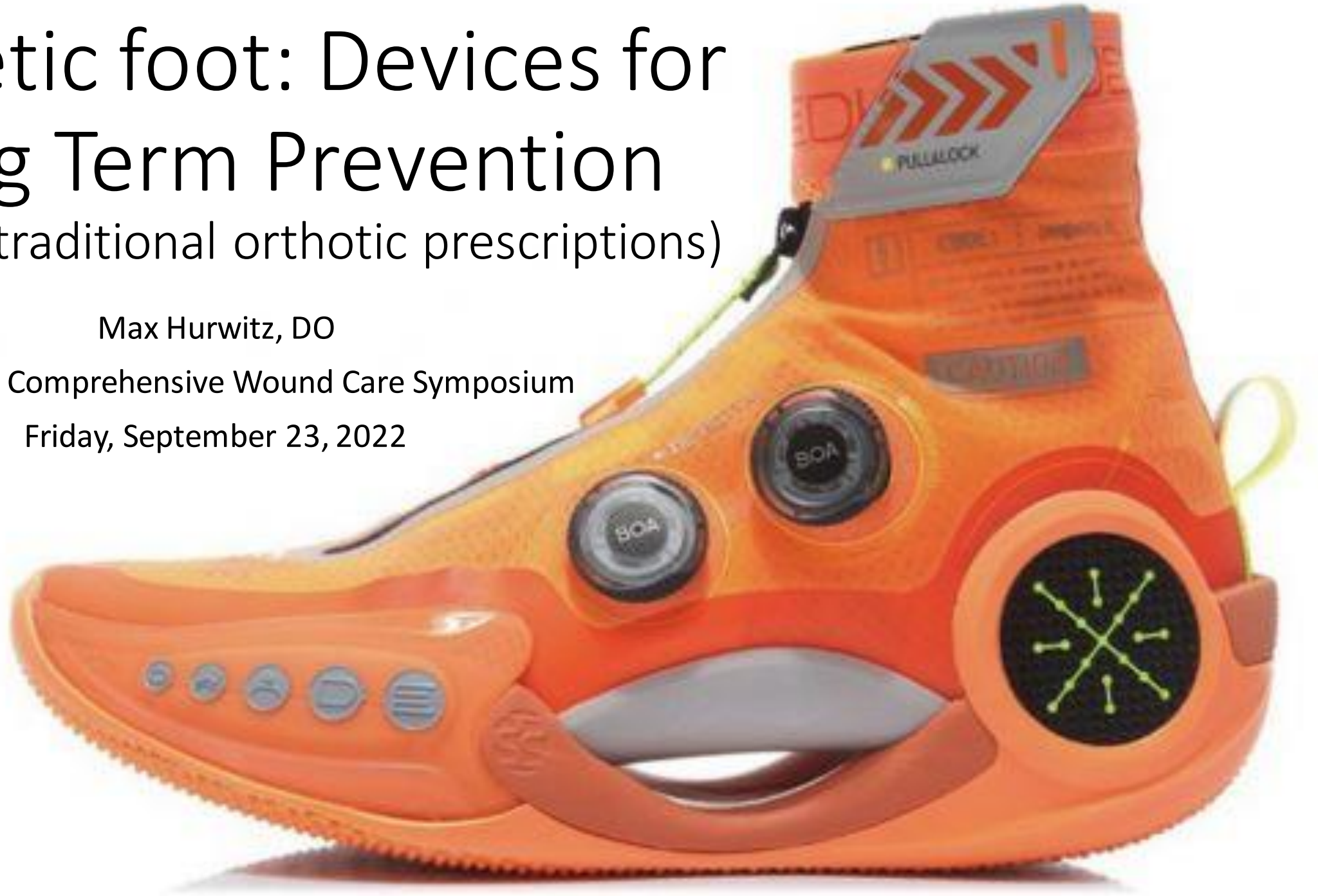

Speaker Disclosure Information

I have no relevant disclosures

80% of diabetes related amputations are preceded by a foot ulcer

¼ of DFUs lead to amputation

Risk of reamputation in diabetic patients stratified by limb and level of amputation

Izumi Y et al. Diabetes Care. 2006

- Reamputation at 1,3, and 5-years
  - Toe: 22.8%, 39.6%, 52.3%
  - Ray: 28.7%, 41.2%, 50%
  - Midfoot: 18.8%, 33.3%, 42.9%
  - Major: 4.7%, 11.8%, 13.3%

Risks for Diabetes related foot ulcer

- Neuropathy
- Peripheral arterial disease
- Foot deformity
- Limited ankle range of motion
- High plantar foot pressures
- Minor trauma
- Previous ulceration
- Prior Amputation
- Vision impairment

Cornerstones of Prevention

- Identification of the at-risk foot
- Regular inspection and examination of the at-risk foot
- Education of patient, family and healthcare providers
- Routine wearing of appropriate footwear
- Treatment of preulcerative signs

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Do shoes and insoles help?

- Custom Molded Insoles:
  - Reduce forefoot plantar pressure
    - metatarsals area (29–50%) midfoot (81%) and known ulcer location (62%)
  - Reduce risk of initial ulceration
  - Reduce the risk of re-ulceration

- Accommodating and Protective Footwear:
  - Decreases peak plantar pressures
  - Rigid rocker soles reduce ulcer recurrence

Custom-Made Orthesis and Shoes in a Structured Follow-Up Program Reduces the Incidence of Neuropathic Ulcers in High-Risk Diabetic Foot Patients

Rizzo L, Tedeschi A, Fallani E, Coppelli A, Vallini V, Iacopi E, Piaggesi A. Int J Low Extrem Wounds. 2012. Mar;11(1):59-64

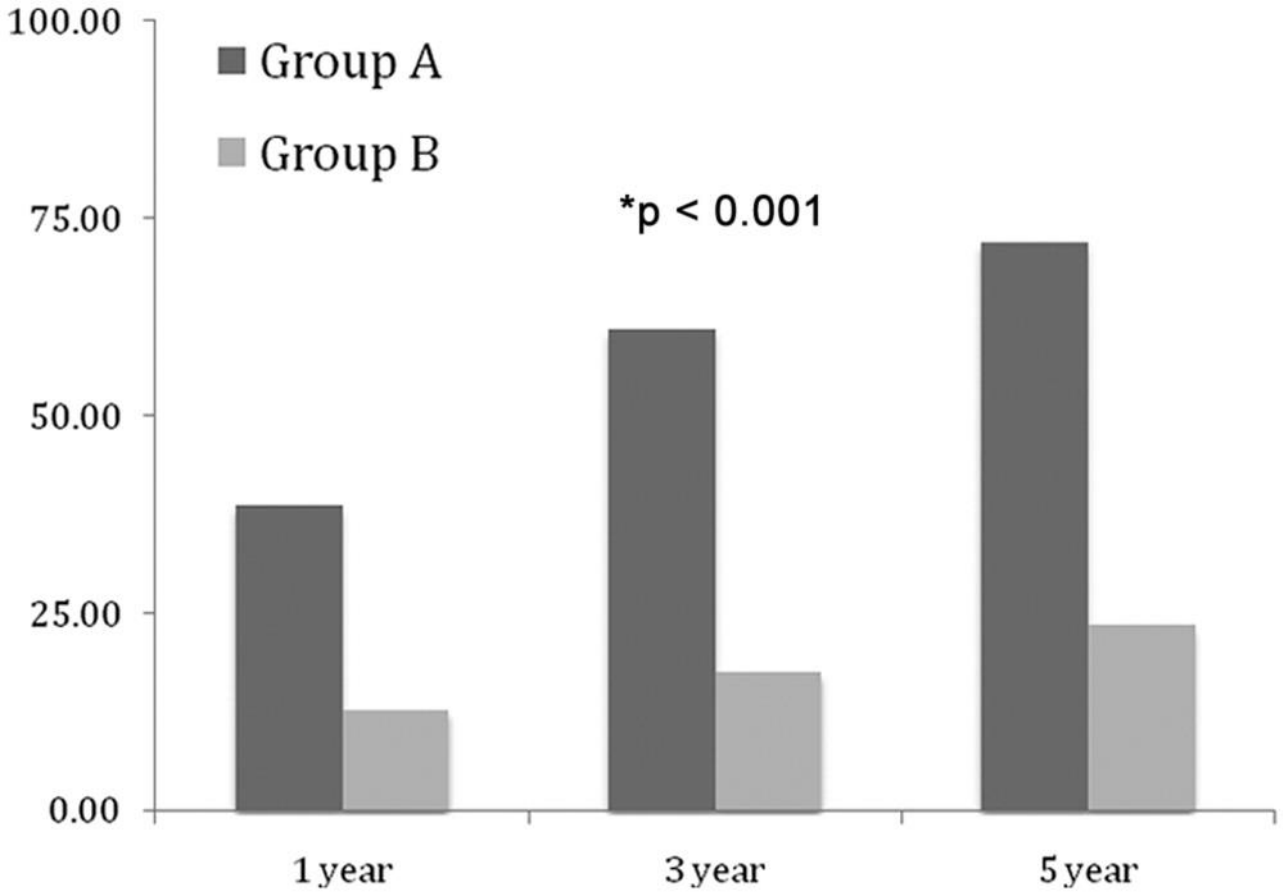


Figure 1. Cumulative incidence of ulcers and recurrences in both groups after 1, 3, and 5 years of follow-up

Footwear – Shoe and Orthosis

Appropriate footwear:

- Neither too tight or too loose
  - Length: Inside should be 1-2cm longer than the foot
  - Width: Should equal the widest part of the foot (metatarsalphalangeal joints)
  - Height: Allow room for all the toe

- Peripheral neuropathy:
  - Insole that distributes forces evenly, reduce shear stress and provide shock absorption

- Decreased joint mobility:
  - Shock absorption in the heel, stiff outsole, rocker-bottom, and insole that distributes weight evenly

Prescription example - Hollow Claw Foot

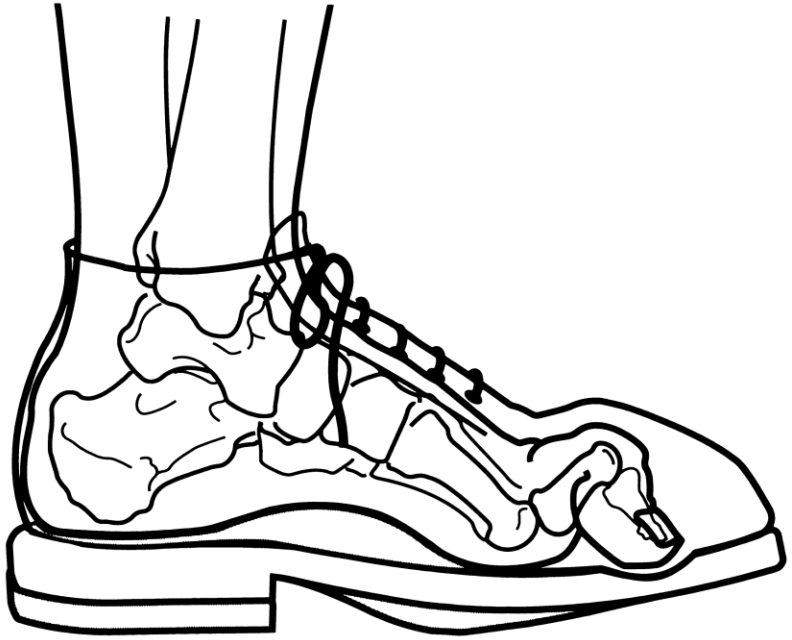


Figure: Shoe with a full-contact insole and a rocker bar with an early pivot point.

- Recommended Prescription:
  - Full contact trilaminar custom insole
  - Stiff outsole
  - Rocker with an early pivot point
  - Heel – shock absorption
  - Ankle high shoe to maintain support

Diabetes Care. 2001;24(4):705-709. doi:10.2337/diacare.24.4.705

How does the shoe impact function?

- Kinematic studies on healthy subjects:
  - Overall walking speed and gait function is maintained
- Balance in patients with DM and neuropathy:
  - Static standing balance is not significantly different that a standard sole
- Patients with DM and a TMA
  - Rigid rocker sole with custom insole improves walking speed and function using the Physical Performance Test

New technology

Custom 3D printed insole with individualized metamaterials for the diabetic foot

- Jing-Sheng Li, Yuri F Hudak, Scott Cullum, Brian M Strzelecki, Chris Richburg, G Eli Kaufman, Daniel Abrahamson, Jeffrey T. Heckman, Beth Ripley, Scott Telfer, William R Ledoux, Brittney C Muir, Patrick M Aubin

- VA Center for Limb Loss and MoBility (CLiMB), VA Puget Sound Health Care System. Department of Mechanical Engineering, University of Washington

- 9th World Congress of Biomechanics (WCB 2022) Taipei, July 10-14 2022

Current standard-of-care insole

Evaluate → Imprint → Casting → Design → Fabrication → Deliver

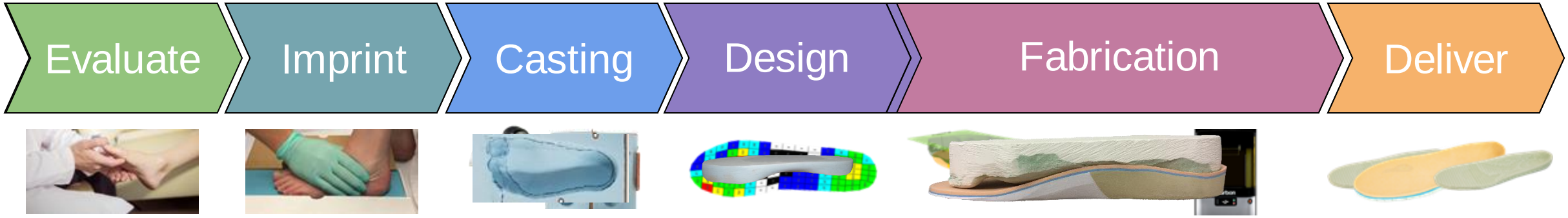




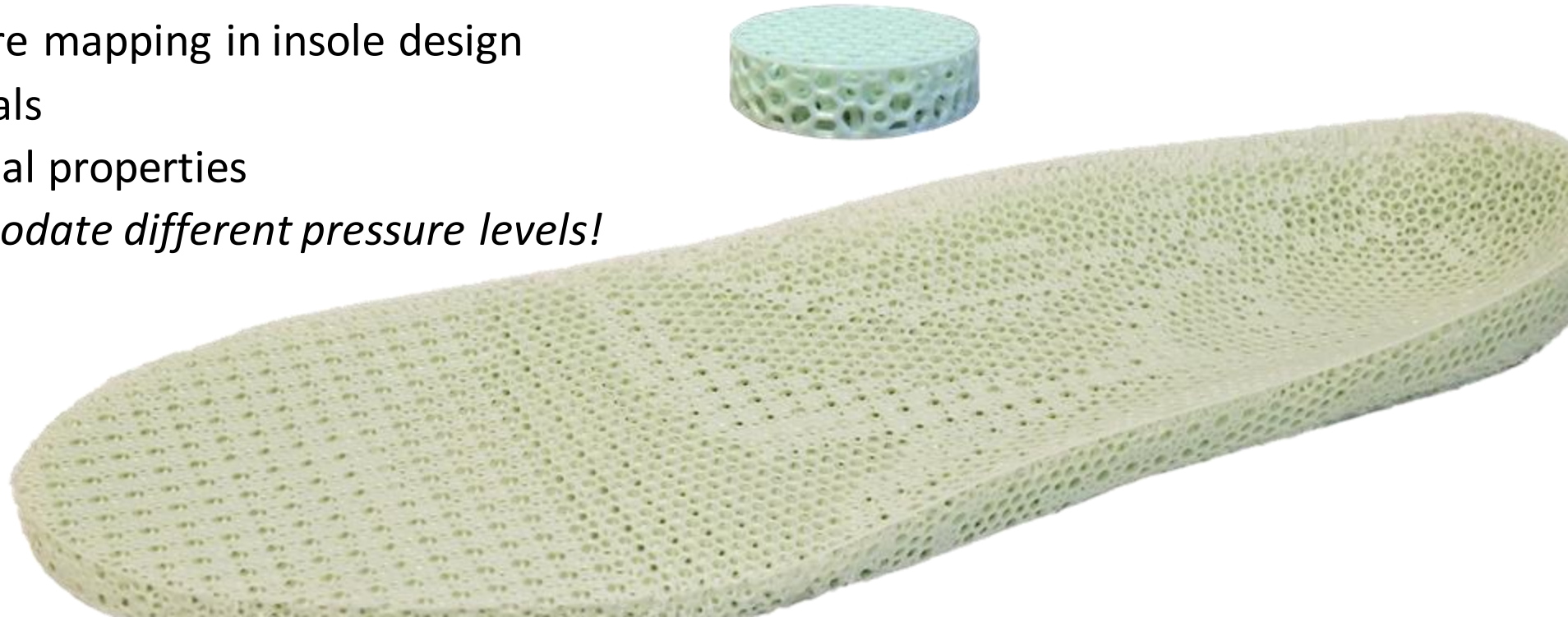

- Pros
  - Individualized foot shape
  - Plastazote-poron-EVA 3-layer materials
    - Different stiffness for better contact and load sharing

- Cons
  - Hard to create multiple pairs at a time
  - Dynamic plantar pressure assessment typically not included in the design process
  - Compress quickly in highly active users

Novel 3D printed insole

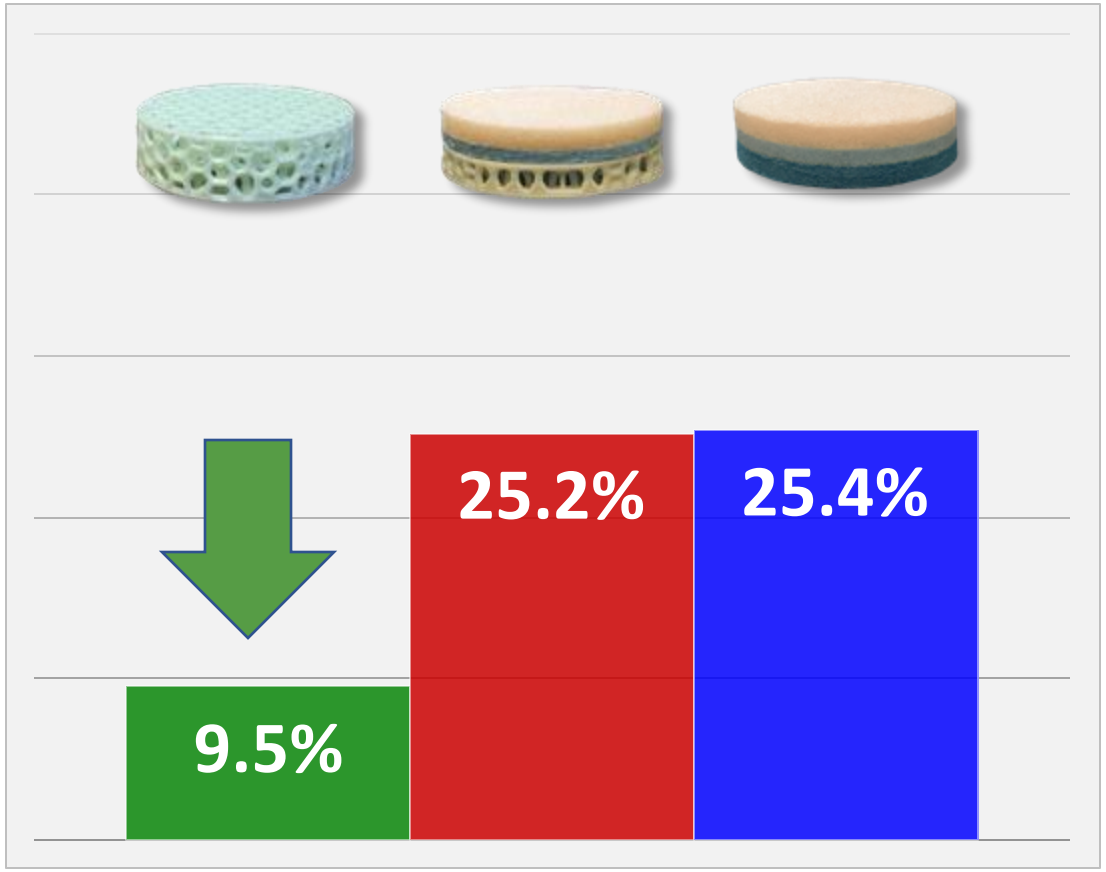


- Known
  - Can include pressure mapping in insole design
  - Use of metamaterials
    - Variable material properties
    - *Better accommodate different pressure levels!*

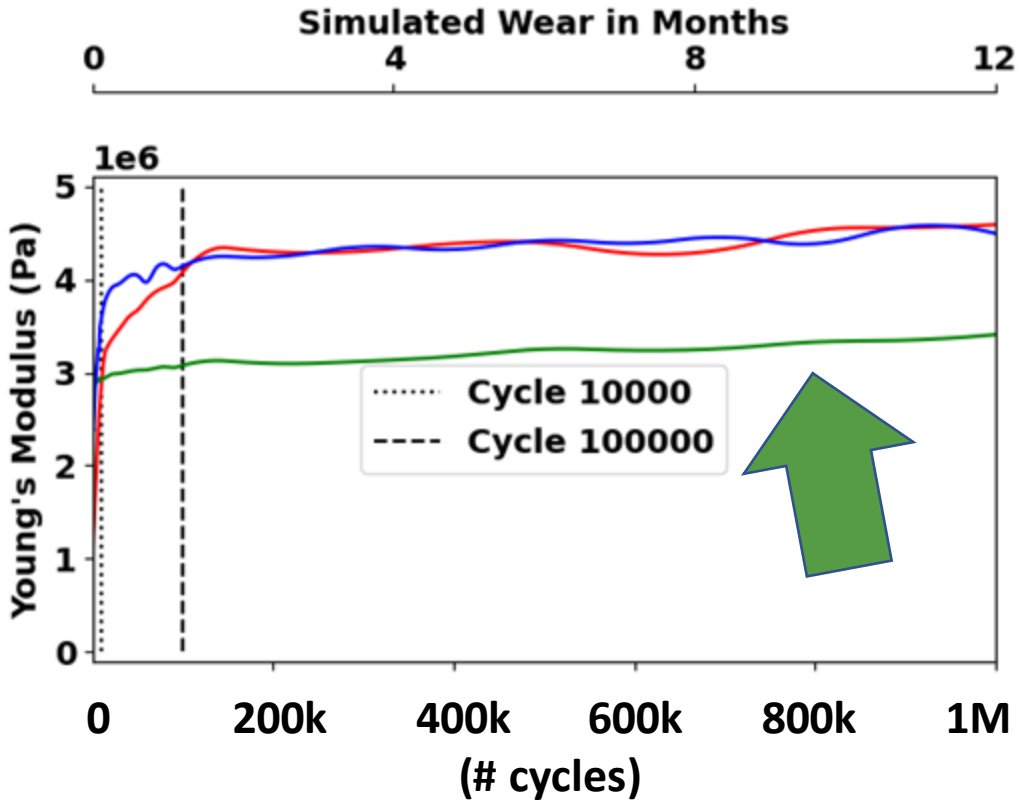


Compressive Durability Testing

- Deformation @ 1M cycle

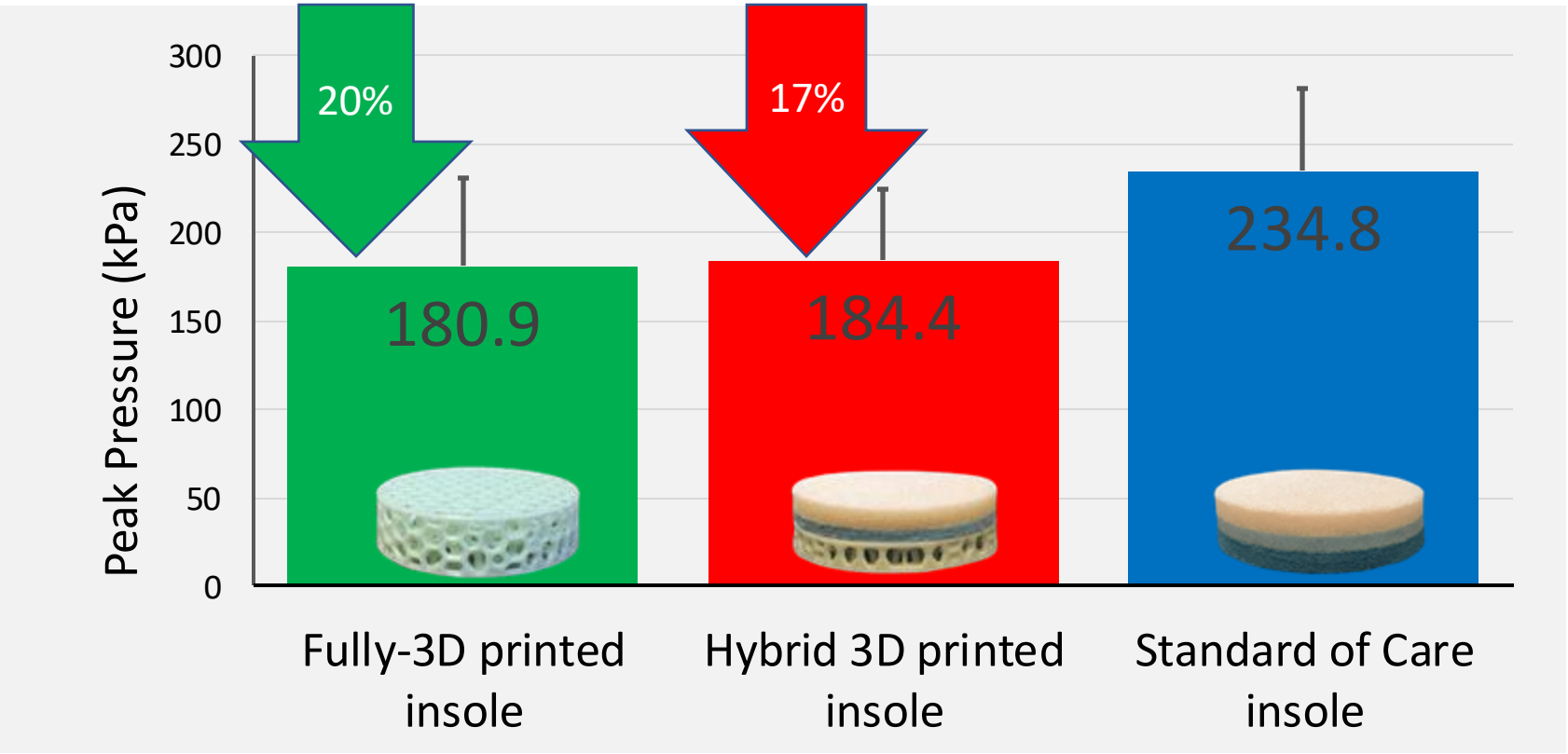


- Stiffness over 1 M cycle



In-vivo biomechanical testing

- N=3 (age 57-71 yr, body height: 165-199 cm, body mass: 70-120 kg, BMI: 25.5-40.2 kg/m^2)
- Skin condition: no adverse event happened



Results

- 3D printed insoles have improved durability compared to the standard-of-care insole.
- 3D printed insole, designed with personalized plantar pressure mapping, successfully unload plantar pressure in the desired region.
- 3D printed insole reduces shear stresses

New advances in temperature monitoring

- Reduces the risk of incident diabetic foot wound in patients with a high risk foot
- Reduces risk of diabetic foot ulcer recurrence
  - Standard care (physician visit every 8 weeks, education and shoe/insert) and for patients instructed to complete twice daily foot exams , are 4.3 and 4.7 times more likely to develop a DFU.

  - Daily temperature measurement (1st, 3rd, 5th metatarsal head, great toe, central foot, and heel) in the morning and evening. If >4F temp differen
    patients reduced daily steps until temp decreased to <4F.

SmartMat

Remotely monitoring patients foot temperature with daily scans

Temperature data is analyzed automatically for differences, and asymmetry > 4F over 2 consecutive uses is deemed an episode

A phone call is made to the patient to discuss next steps, including offloading, foot exam, or clinic follow up

Lower resource utilization for patients with healed diabetic foot ulcers during participation in a prevention program with foot temperature monitoring.

Isaac AL, et al. BMJ Open Diabetes Res Care. 2020

- Study program:
  - Once daily foot temperature monitoring with a Smart Mat device. If the temperature is 2.2C over two consecutive uses prompted an intervention by the study team.
  - Evaluated 2 years prior to intervention, 1 year or participation and 1 year after.
- Results
  - Hospitalizations: 0.52 RRR
  - Lower extremity amputations: 0.71 RRR
  - All foot ulcers: 0.46 RRR

Does this work after an amputation?

- **Unilateral remote temperature monitoring to predict future ulceration for the diabetic foot in remission. Lavery et al. 2019**
  - Patients with a prior amputation and history of DFU
  - Using a temperature monitoring foot mat, able to predict 91% of DFUs >4 weeks prior to occurrence

Thank you!

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