Foot Orthoses for Patients with Diabetes

In this session…

- Indications
- Objectives
- Styles of “Diabetic” Foot Orthoses
- Features of Foot Orthoses
- Medicare TSPD Coverage
- Diabetic FO Research

Who needs therapeutic inserts?

Category	Category 0	Category 1	Category 2	Category 3
Characteristics	Normal Plantar Sensation	Loss of Protective Sensation (LOPS)	LOPS with either High Pressure or Poor Circulation or Structural Foot Deformities or Onychomycosis	History of Ulceration, Amputation or Neuropathic Fracture
Risk	Low	Moderate	High	Very High
Treatment Plan	Patient education, daily inspection, proper footwear, routine foot care as needed, yearly follow-up. Tight glycemic control necessary to maintain this risk category.	Patient education, proper footwear, soft molded insoles, routine foot care as needed, daily self-inspection, 6 month follow-up	Patient education, proper footwear with possible modifications, custom molded insoles fitted into footwear with possible modification to relieve areas of pressure, scheduled routine foot care, daily self-inspection, 3 month follow-up	Patient education, extra depth footwear with custom modification, custom molded insoles with modifications to relieve pressure, offload with cast as necessary, scheduled routine foot care, daily self-inspection, monthly follow-up

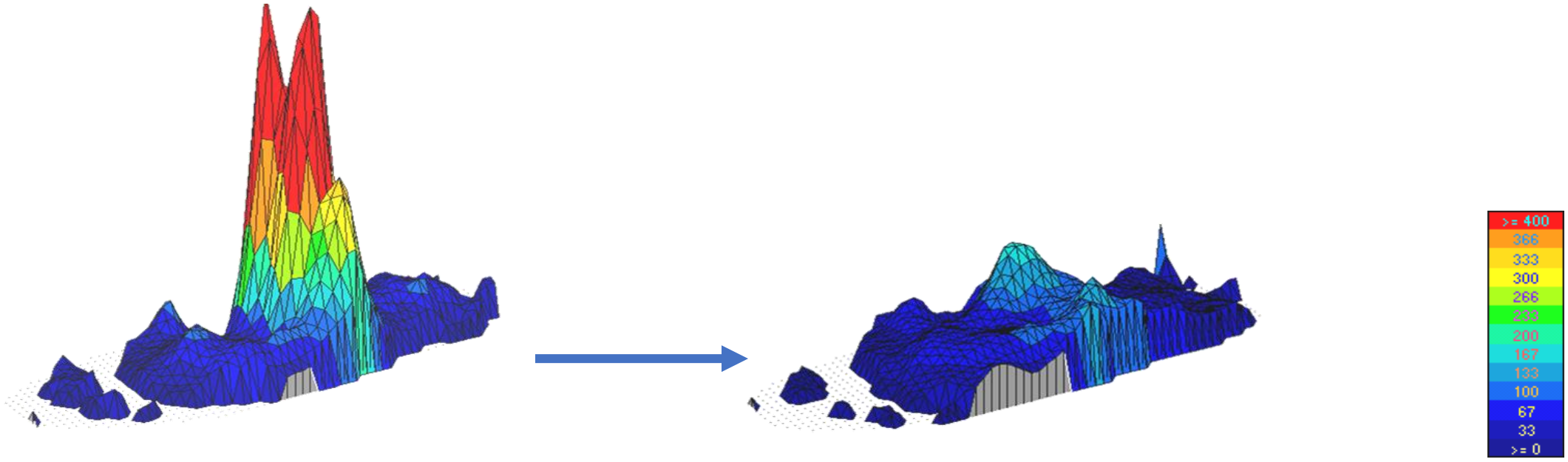
International Diabetes Federation

Indications

- Diabetes
  - Or other condition that causes peripheral neuropathy
- Peripheral neuropathy
  - Loss of protective sensation
- Foot deformity
- Signs of pressure/friction on plantar foot
  - Calluses, red spots, blisters
- History of foot ulcers
- History of Charcot arthropathy
- History of partial foot amputation

Objectives of Treatment

- Reduce areas of high peak plantar pressures
- Redistribute plantar pressures as evenly as possible
- Reduce friction and shear forces on plantar foot



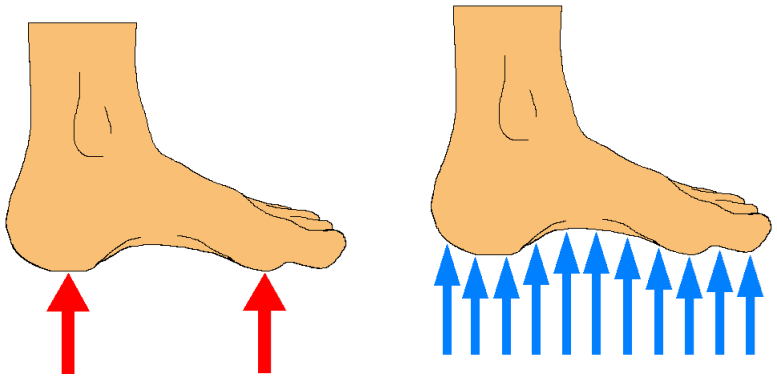
Shoe w/ factory insole

Shoe w/ custom TCO

Types of Foot Orthoses for Patients with Diabetes

Foot Orthoses

- Prefabricated heat-moldable inserts
  - Appropriate in the *absence of*:
    - Peripheral neuropathy
    - Foot deformity
    - History of ulcers
    - History of Charcot
- Custom accommodative foot orthoses
  - Total contact, primarily cushioning
- Custom semi-rigid foot orthoses
  - Total contact, weight redistribution/offloading
- Partial foot prosthesis
  - Protect residual foot



Medicare Coverage

Medicare

- Footwear (shoes and inserts) for persons with diabetes is often viewed as a “Medicare thing”.
- While Medicare does provide coverage for therapeutic footwear for eligible beneficiaries, all at-risk diabetic feet require proper therapeutic footwear.
- Oftentimes, other third-party payors use Medicare as their model when comes to including or excluding certain items for coverage, but there is no hard and fast rule on this. Verify coverage on every patient (if your practice is one that works with insurances).

Medicare Benefit and Eligibility

- Therapeutic Shoes for Persons with Diabetes (TSPD) benefit
  - Signed into law in 1987, benefit went live in 1993
- Allows coverage for one pair of shoes and three pairs of inserts every c*alendar* year.
  - A5500(2) + A5512, A5513 or A5514(6)
  - A5501(2) + A5512, A5513 or A5514(4)
  - Certain shoe modifications may be substituted for inserts

Medicare Benefit and Eligibility

- Patient must have Medicare Part B
- Patient must have diabetes
- Patient must have at least one of six qualifying foot conditions:
  a) Previous amputation of the other foot, or part of either foot, or
  b) History of previous foot ulceration of either foot, or
  c) History of pre-ulcerative calluses of either foot, or
  d) Peripheral neuropathy with evidence of callus formation of either foot, or
  e) Foot deformity of either foot, or
  f) Poor circulation in either foot.

A5510: Direct-formed, compression molded to patient's foot *without* external heat source, multi-density insert(s), prefabricated, per shoe *(Not a reimbursable code)*

A5512: Multiple-density insert, direct-formed, molded to foot after external heat source of 230°F, or higher, total contact with patient's foot, including arch, base layer minimum of 1/4" material of Shore A 35 Durometer or 3/16" material of Shore A 40 Durometer (or higher), prefabricated, each

A5513: Multiple-density insert, custom-molded from **model of patient's foot**, total contact with patient's foot, including arch, base layer, minimum of 3/16" material of Shore A 35 Durometer (or higher), including arch filler and other shaping material, custom fabricated, each

A5514: Multiple-density insert, made by **direct carving** with CAM technology from a rectified CAD model created from a digitized scan of the patient total contact with patient's foot, including arch, base layer, minimum of 3/16" material of Shore A 35 Durometer (or higher), and other shaping material, custom fabricated, each

L5000: Partial foot, shoe insert with longitudinal arch, toe filler; for beneficiaries missing digits, particularly the hallux (great toe), or the forefoot, designed to provide standing balance and toe off support for improved gait. The biomechanical control differs from the foot-protective function provided by inserts used as part of diabetes management.

Materials

A **durometer** is the instrument used to measure the hardness or softness of materials.

The numerical readings from the durometer are also referred to as the “durometer” of the material.
The durometer reading increases with the hardness of the material.

Closed Cell Polyethylene (Plastazote®)

Used for diabetic and arthritic foot care needs

Pink

- Non-allergenic, lightweight, and can be used in direct contact with the skin
- Heat moldable, grindable
- Molds quickly to the foot during weight bearing, enhancing total contact

White

- Retains cushion longer than pink
- More supportive than pink

Ethylene Vinyl Acetate Foam (EVA)

An elastomeric polymer that produces materials which are "rubber-like" in softness and flexibility

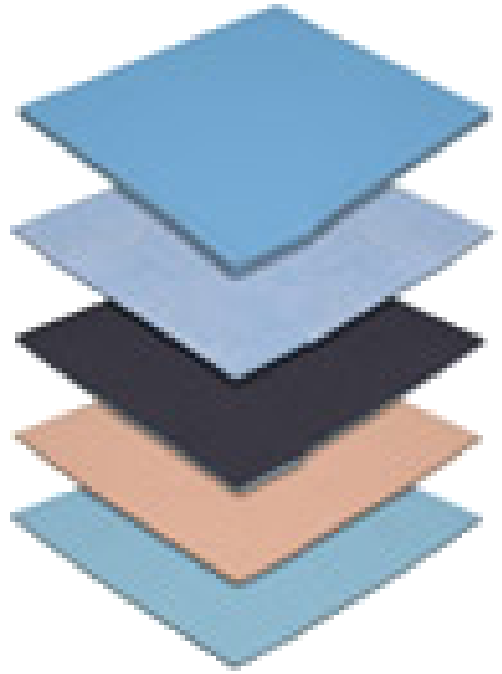
- Grindable
- Heat Moldable
- Glueable
- Heat molding temp. 250°-300 °
- Varying durometers and colors
- White (55) and Yellow (45)

Urethanes (PPT®/Poron®)

Breathable, lightweight, non-allergenic, and resists bottoming out under long-term wear; shock absorbency

Grindable and glues easily to all other orthotic and prosthetic materials.

Low durometer: 10-15



Cork Composite

Moldable material that makes a superior shell for a foot orthosis

Holds its shape and does not bottom out, yet absorbs shocks and impact

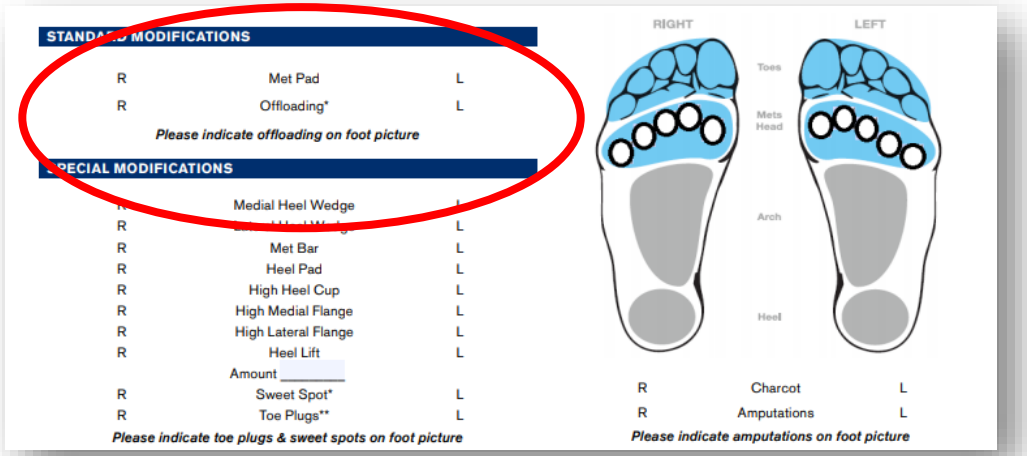
- Moldable
- Grindable and glueable
- 55 durometer
- More rigid support

Low Friction Interface

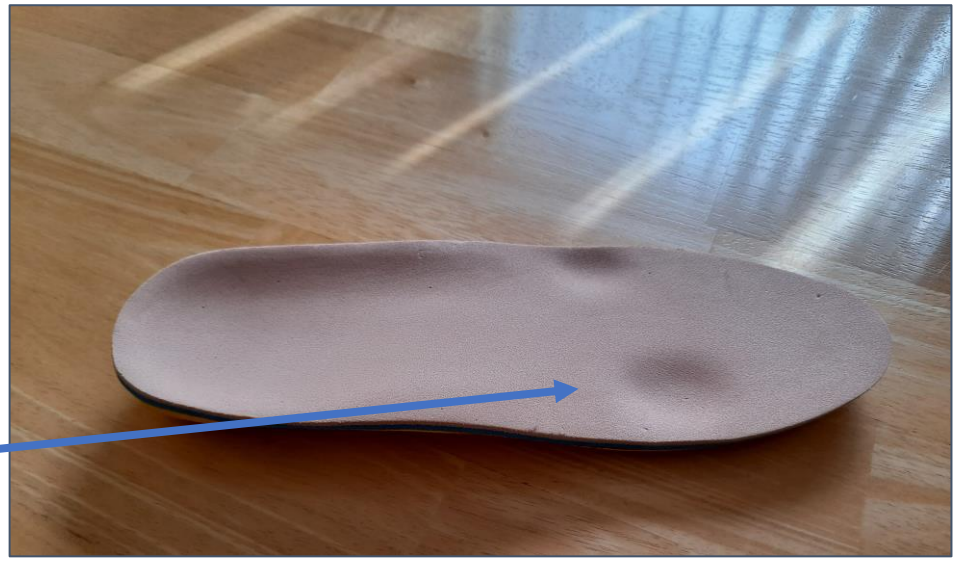
- ShearBan®
  - Self-adhesive
  - Can be heat-molded
  - Available in sheets and pre-cut shapes

  - ShearBan® works by reducing friction only in specific, at-risk areas of footwear, insoles, medical devices and sports equipment to protect sensitive tissue from wound-causing friction. This is called *Strategic Friction Reduction*. Friction is retained in surrounding areas to optimize mobility and stability for users.

Modifications/Add-ons

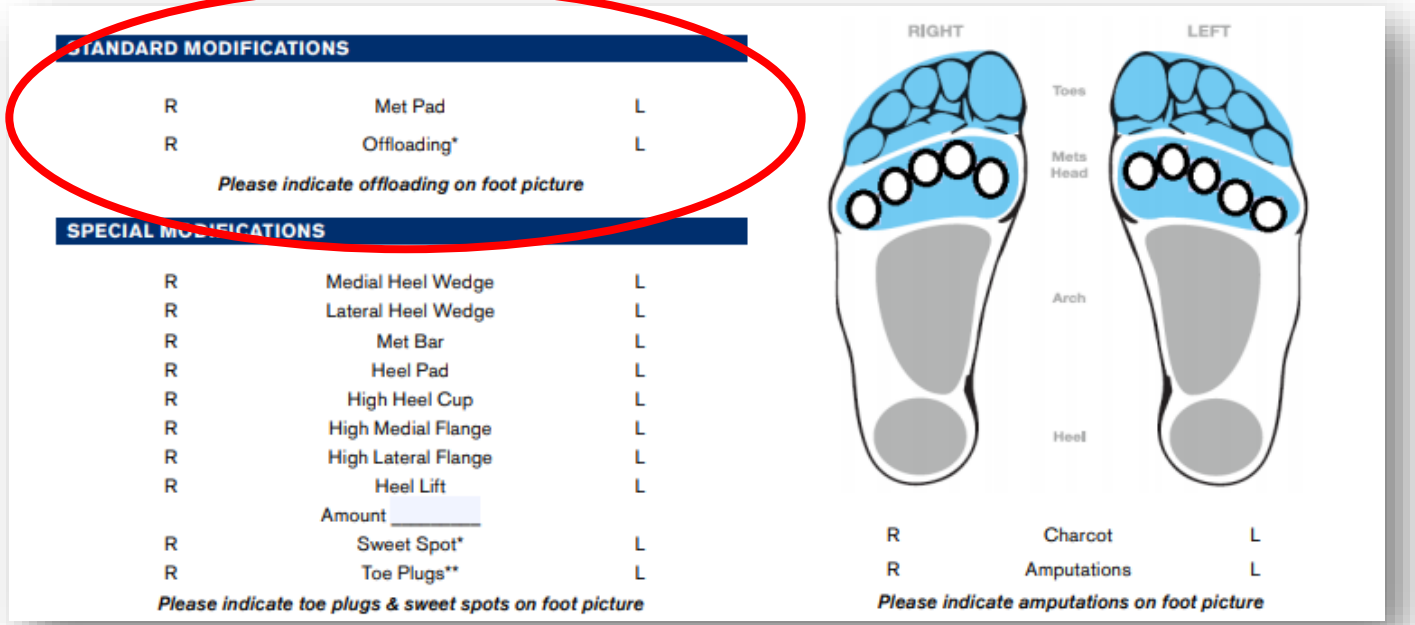


Offloading – Depression in the insert



“Sweet Spot” – Cutout in base backfilled with softer foam

- Cushioning placed directly below the metatarsal heads (possibly slightly distal)
- Transferring weight bearing away from the affected area
- Used for: metatarsal pain, ulcerations, callouses



STANDARD MODIFICATIONS

R		L
R	Met Pad	L
R	Offloading*	L

Please indicate offloading on foot picture

SPECIAL MODIFICATIONS

R		L
R	Medial Heel Wedge	L
R	Lateral Heel Wedge	L
R	Met Bar	L
R	Heel Pad	L
R	High Heel Cup	L
R	High Medial Flange	L
R	High Lateral Flange	L
R	Heel Lift	L
	Amount _____	
R	Sweet Spot*	L
R	Toe Plugs**	L

Please indicate toe plugs & sweet spots on foot picture

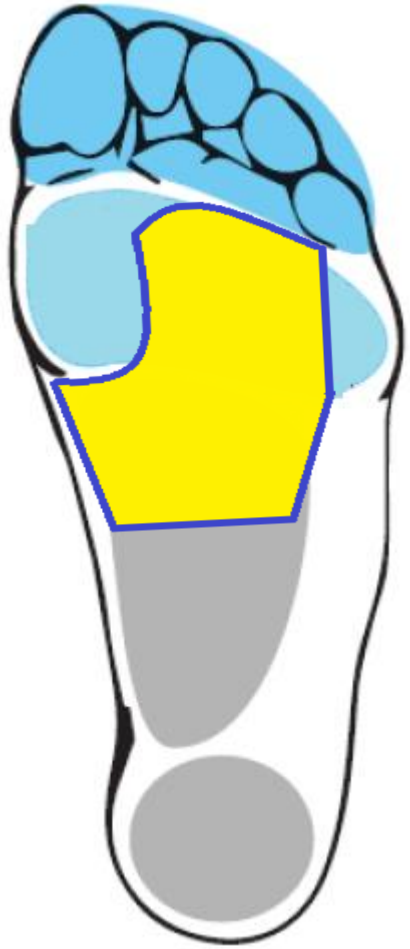
R		L
R	Charcot	L
R	Amputations	L

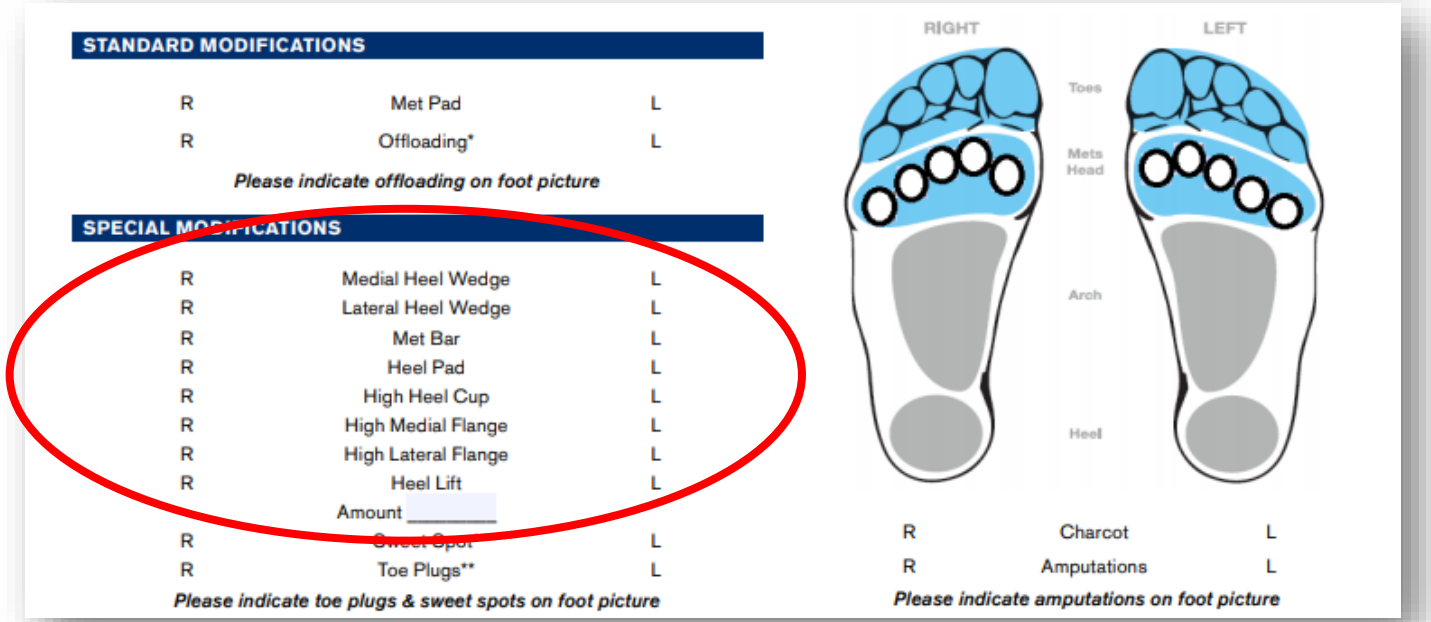
Please indicate amputations on foot picture

Offloading - Dancer pad

Transferring weight bearing away from the affected area by *loading up the lesser metatarsals*

Used for: metatarsal pain, ulcerations, callouses





STANDARD MODIFICATIONS

R	Met Pad	L
R	Offloading*	L

Please indicate offloading on foot picture

SPECIAL MODIFICATIONS

R	Medial Heel Wedge	L
R	Lateral Heel Wedge	L
R	Met Bar	L
R	Heel Pad	L
R	High Heel Cup	L
R	High Medial Flange	L
R	High Lateral Flange	L
R	Heel Lift	L

Amount _____

R	Sweet Spot	L
R	Toe Plugs**	L

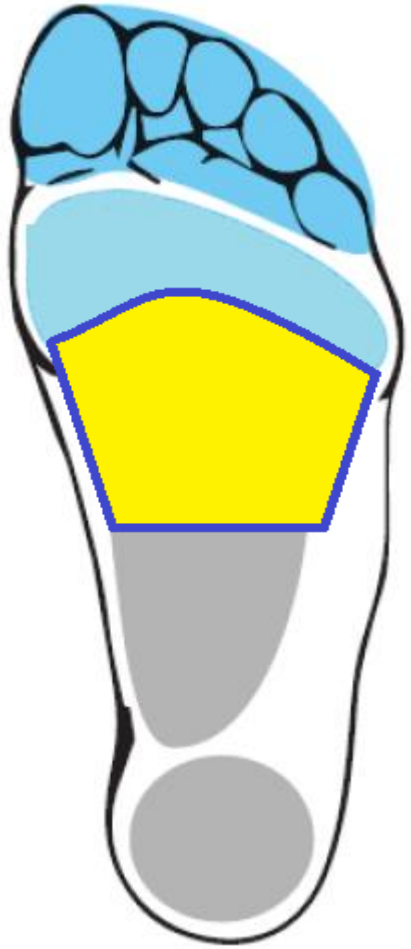
Please indicate toe plugs & sweet spots on foot picture

R	Charcot	L
R	Amputations	L

Please indicate amputations on foot picture

Metatarsal Bar

- Placed proximal to the metatarsal heads
- Transferring the weight bearing surface to the shafts of the metatarsals
- Creating a “shelf” like system to offload
- Used for: metatarsal pain, ulcerations, callouses



Diabetic Insert Research

Insert Features – Met Pads

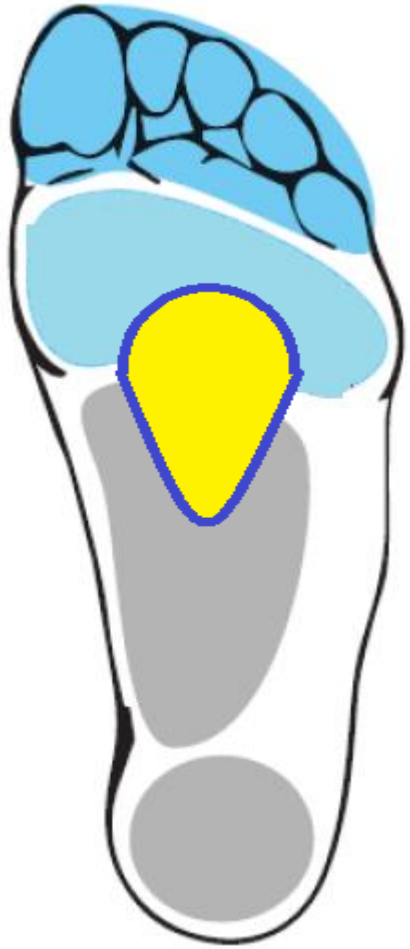
- Hastings MK, Mueller MJ, Pilgram TK, Lott DJ, Commean PK, Johnson JE. **Effect of metatarsal pad placement on plantar pressure in people with diabetes mellitus and peripheral neuropathy.** Foot Ankle Int. 2007 Jan;28(1):84-8.

- **BACKGROUND:** Standard prevention and treatment strategies to decrease peak plantar pressure include a total contact insert with a metatarsal pad, but no clear guidelines exist to determine optimal placement of the pad with respect to the metatarsal head. The purpose of this study was to determine the effect of metatarsal pad location on peak plantar pressure in subjects with diabetes mellitus and peripheral neuropathy.
- **METHODS:** Twenty subjects with diabetes mellitus, peripheral neuropathy, and a history of forefoot plantar ulcers were studied (12 men and eight women, mean age=57+/-9 years). CT determined the position of the metatarsal pad relative to metatarsal head and peak plantar pressures were measured on subjects in three footwear conditions: extra-depth shoes and a 1) total contact insert, 2) total contact insert and a proximal metatarsal pad, and 3) total contact insert and a distal metatarsal pad. The change in peak plantar pressure between shoe conditions was plotted and compared to metatarsal pad position relative to the second metatarsal head.
- **RESULTS:** Compared to the total contact insert, all metatarsal pad placements between 6.1 mm to 10.6 mm proximal to the metatarsal head line resulted in a pressure reduction (average reduction=32+/-16%). Metatarsal pad placements between 1.8 mm distal and 6.1 mm proximal and between 10.6 mm proximal and 16.8 mm proximal to the metatarsal head line resulted in variable peak plantar pressure reduction (average reduction=16+/-21%). Peak plantar pressure increased when the metatarsal pad was located more than 1.8 mm distal to the metatarsal head line.
- **CONCLUSIONS:** Consistent peak plantar pressure reduction occurred when the metatarsal pad in this study was located between 6 to 11 mm proximal to the metatarsal head line. Pressure reduction lessened as the metatarsal pad moved outside of this range and actually increased if the pad was located too distal of this range. Computational models are needed to help predict optimal location of metatarsal pad with a variety of sizes, shapes, and material properties.

Insert Features – Met Pads

- Mueller MJ, Lott DJ, Hastings MK, Commean PK, Smith KE, Pilgram TK. **Efficacy and mechanism of orthotic devices to unload metatarsal heads in people with diabetes and a history of plantar ulcers .** Phys Ther. 2006 Jun;86(6):833-42.

- **BACKGROUND AND PURPOSE:** Total-contact inserts (TCIs) and metatarsal pads (MPs) frequently are prescribed to reduce excessive plantar stresses to help prevent skin breakdown in people with diabetes mellitus (DM) and peripheral neuropathy. The first purpose of this study was to determine the effect of a TCI and an MP on metatarsal head peak plantar pressures (PPP) and pressure-time integrals (PTI).
- **METHODS:** A repeated-measures research design was used, and outcome measures are reported for 3 footwear conditions: shoe, shoe with TCI, and shoe with TCI and MP. In-shoe plantar pressures were collected during walking and during spiral x-ray computed tomography (SXCT). The STT and identification of the pressure sensor and location of the MP in relationship to the metatarsal heads were determined by use of SXCT.
- **RESULTS:** The PPP and the PTI were 16% to 24% lower at the metatarsal heads in the TCI condition than in the shoe condition. The PPP and the PTI decreased an additional 15% to 28% (for a total reduction of 29% to 47%) with the addition of the MP. The contact area increased 27% with the TCI but not with the MP. The STT did not increase under the metatarsal heads in the TCI condition (compared with the shoe condition) but did increase 8% to 22% at metatarsal heads 2 to 5 with the addition of the MP. The PPP increased substantially (308%) and the STT decreased 14% under the shaft of the second metatarsal with the addition of the MP to the TCI-plus-shoe condition.
- **DISCUSSION AND CONCLUSION:** The TCI and the MP caused substantial and additive reductions of pressures under the metatarsal heads. The TCI reduces excessive pressures at the metatarsal heads by increasing the contact area of weight-bearing forces. Conversely, the MP acts by compressing the soft tissues proximal to the metatarsal heads and relieving compression at the metatarsal heads. These findings can assist in the design of effective orthotic devices to relieve excessive plantar stresses that contribute to skin breakdown and subsequent amputation in people with DM and peripheral neuropathy.



Shoes and Foot Orthoses

- Randomized trial of custom orthoses and footwear on foot pain and plantar pressure in diabetic peripheral arterial disease.
  - Burns J, Wegener C, Begg L, et al. Diabet Med. 2009 Sep;26(9):893-9
  - CONCLUSIONS: Custom foot orthoses significantly reduced plantar pressure compared with the sham, but there were no significant differences between groups for pain or function. The high-quality walking footwear provided to both groups may explain this finding. Footwear should have greater emphasis as the clinical intervention.

Foot Orthoses

- Effect of footwear and orthotic devices on stress reduction and soft tissue strain of the neuropathic foot.
  - Lott DJ, Hastings MK, Commean PK, Smith KE, Mueller MJ. Clin Biomech (Bristol, Avon). 2007 Mar;22(3):352-9.
  - INTERPRETATION: Footwear orthotic devices tested in this study decreased pressure and soft tissue strain at the second ray of the foot, and these two variables were strongly related

Foot Orthosis Design

- Prevention of Recurrent Foot Ulcers with Plantar Pressure-based In-shoe Orthoses: The CareFUL Prevention Multicenter Randomized Controlled Trial
  - Ulbrecht JS, Hurley T, Mauger DT, Cavanaugh PR. Diabetes Care. 2014 Jul;37(7):1982-9.
  - Shape- and pressure-based FOs Vs A5513 FOs
  - Trend across the entire 15-month follow-up period in favor of experimental FO
  - Shape- and barefoot plantar pressure-based FOs were more effective in reducing submetatarsal head plantar pressure and ulcer recurrence.

- # Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review
    - van Netten JJ, Price PE, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Bus SA; International Working Group on the Diabetic Foot. Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. Diabetes Metab Res Rev. 2016 Jan;32 Suppl 1:84-98. doi: 10.1002/dmrr.2701. PMID: 26340966.
- **Results:** From the identified records, a total of 30 controlled studies (of which 19 RCTs) and another 44 non-controlled studies were assessed and described. Few controlled studies, of generally low to moderate quality, were identified on the prevention of a first foot ulcer. For the prevention of recurrent plantar foot ulcers, multiple RCTs with low risk of bias show the benefit for the use of daily foot skin temperature measurements and consequent preventative actions, as well as for therapeutic footwear that demonstrates to relieve plantar pressure and that is worn by the patient. To prevent recurrence, some evidence exists for integrated foot care when it includes a combination of professional foot treatment, therapeutic footwear and patient education; for just a single session of patient education, no evidence exists. Surgical interventions can be effective in selected patients, but the evidence base is small.
- **Conclusion: The evidence base to support the use of specific self-management and footwear interventions for the prevention of recurrent plantar foot ulcers is quite strong**, but is small for the use of other, sometimes widely applied, interventions and is practically nonexistent for the prevention of a first foot ulcer and non-plantar foot ulcer.

Why is shear important?

- Pressure + Shear Force (Friction) = Skin Breakdown
- Microclimate = Increased Pressure and Shear Force
- Microclimate, including localized temperature and moisture, influences the susceptibility of skin and soft tissues to the effects of pressure, shear, and friction
  - Moisture reduces epidermis corneum strength (fractures easier)
  - Moisture increases coefficient of friction (increased traction on skin)
  - Better evaporation cools, reducing cell metabolic rate (cells live longer)
  - Extremes of localized temperature reduces epidermis corneum strength (fractures easier)
- Dr. Naylor described this phenomenon in the 1950's, but the pedorthic and diabetic shoe fitter world has been slow to catch on.

Shear in persons with diabetes

- de Wert LA, Geerts M, van der Brug S, Adriaansen L, Poeze M, Schaper N, Bouvy ND. **The Effect of Shear Force on Skin Viability in Patients with Type 2 Diabetes.** J Diabetes Res. 2019 Nov 4;2019:1973704.

- **FINDINGS:** Reactive hyperaemia and IL-1α release was significantly increased after shear loading in all three groups and was higher compared to the responses to pressure loading. The reactive hyperaemic response after shear loading was impaired in patients with type 2 DM compared to healthy participants but did not differ between patients with and without DNP. The reactive hyperaemic response was negatively correlated with the blood glucose level but did not correlate with the DNP severity score.

- **INTERPRETATION:** Shear is important in the development of tissue damage, but the reparative responses to shear are impaired in patients with type 2 DM. DNP was not associated with altered skin responses, suggesting that the loss of protective sensation to sense shear to skin remains a key factor in the development of diabetic foot ulcers in patients with DNP.

How do we decrease shear?

- Socks
  - Avoid 100% cotton socks.
  - Socks should be an acrylic blend.
  - Smooth inside, no prominent seams
- Shoe-Foot Interface
  - Need total contact to reduce movement
  - Heated and molded heat-moldable insert
  - Custom diabetic insert or TCO
  - Consider ShearBan
- Proper shoe fit

The End