

Material Science

In this session...

- What is a durometer?
- Foot orthosis materials and their properties
- Types of foot orthoses
- Methods of manufacture

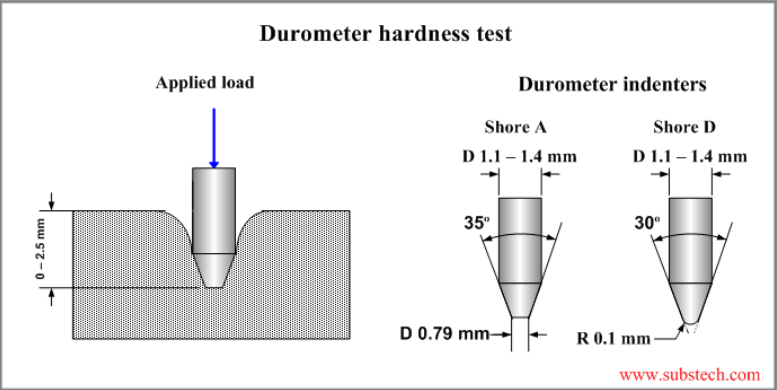
Durometer Measurement

Durometer

- **What exactly is a Shore A durometer mean?**
 - Hardness may be defined as a material's resistance to permanent indentation. The durometer scale was defined by Albert F. Shore, who invented the durometer device in the 1920s.
- **How do you physically measure a material's hardness?**
 - The different Shore Hardness scales measure the resistance of a material to indentation. A 'Shore Hardness' gauge has a needle on a spring protruding from one end. The needle is placed against the rubber or plastic and pressure is applied. Once the gauge is pressed firmly against the material and the needle has penetrated as far as it can go, the measurement needle will indicate the corresponding hardness measurement.



Shore Hardness Testing

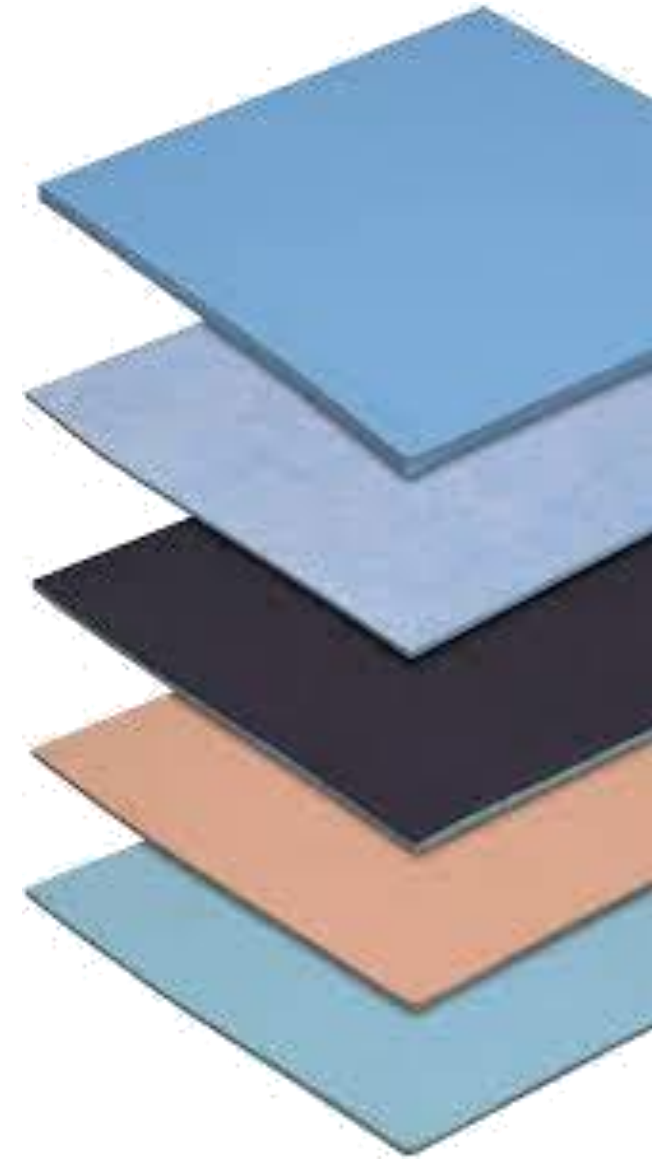


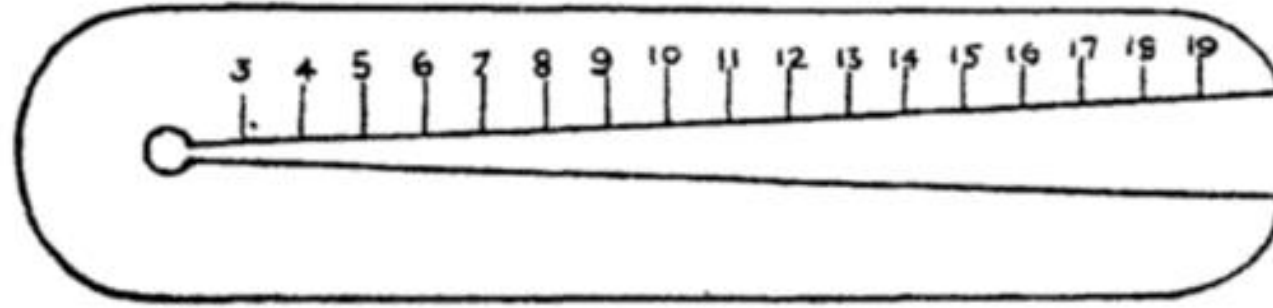
Remember...the larger the number, the harder the material.

Shore A Durometer



- Poron® 3
- Plastazote® #1 15
- AliPlast™ 23
- P-Cell™ 20-25
- Plastazote® #2 25
- UcoLite™ 35
- Medium Pelite 37
- EVA soling 45
- Multicork 55-60
- Plastazote® #3 60
- Ripple soling 75





Irons

Unit of measure. One iron equals $\frac{1}{48}^{\text{th}}$ inch

Ex: A sole that measures 12 irons is $\frac{1}{4}$ inch thick

Foot Orthosis Materials

Semi-rigid and Accommodative

Types of Materials

- CL-PE – Cross-Linked Polyethylene foams
 - Ex.
 - Plastazote(1,2,&3), Pelite, Nickelplast, Medazote, Aliplast
 - Can be soft or semi-rigid
 - 250 - 300 °F for 30 seconds - 2 minutes
 - 20 - 65 durometer (Shore A)
 - Bottoms-out quickly
 - Heat moldable
 - Closed-cell (larger cells)
 - Conforms to foot quickly



Types of Materials

- E.V.A. – Ethylene Vinyl Acetate
 - Ex.
 - Microcell Puff, Sky, Cirrus, Cloud, Ucolite, EFM
 - Can be soft or semi-rigid
 - 225 – 300 °F for 30 seconds – 2 minutes
 - 20 – 75 durometer
 - Heat-moldable
 - Closed-cell (Smaller cells)
 - Increased longevity over PE foams
 - Very good shock absorption



Types of Materials

- Thermoplastic Corks

- EVA substrate
 - Ucocork, Thermocork-lite, Multicork, Easy mold cork
- Natural latex substrate
 - Birkocork, Thermocork
- 275 °F for 2 – 4 minutes
- 55 – 60 durometer
- Can be semi-rigid or rigid
- Heat Moldable
- Very supportive
- Offers shock absorption
- Can be very lightweight
- Different densities based on composition



Types of Materials

- P.U. – Polyurethane Foams
 - Ex.
 - PPT, Poron
 - Soft
 - Not heat moldable
 - 15 durometer
 - Open-cell
 - Good shock absorber
 - Great shear reducer
 - Does not bottom-out quickly



Types of Materials

- Expanded Rubber
 - Ex.
 - Closed cell – Spenco
 - Can maintain 90% of thickness under heavy loads
 - Relatively firm, “cushiony”
 - Cannot be molded
 - May be allergenic
 - Open cell – Lynco
 - Available in different densities
 - Does not bottom-out quickly
 - Not heat moldable



Types of Materials

- Compressed Wool Felt
 - Not moldable
 - Semi-rigid
 - Compresses very quickly
 - Gets harder as it compresses



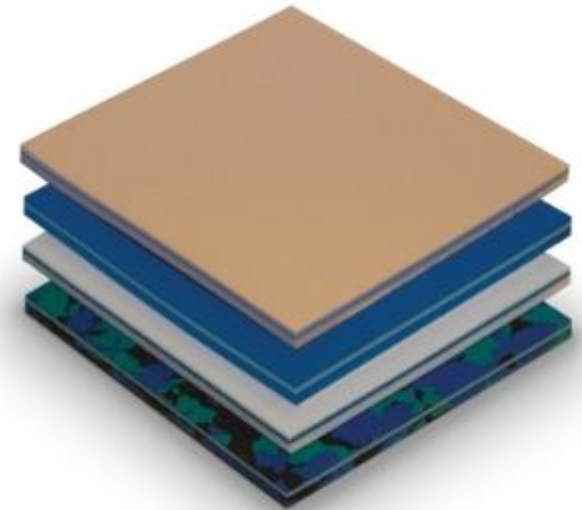
Types of Materials

- Leather
 - Can be rigid or soft
 - Variety of thickness
 - Varying degrees of stiffness
 - Formable, but not heat-moldable
 - No cushioning effects
 - Can be used as a base or a topcover



Types of Materials

- Multidurorometer Laminates
 - Combinations of CL-PE, PU, EVA
 - Maximize the individual properties of each material
 - Reduce cement exposure
 - Increase time efficiency



Rigid (Functional) Foot Orthoses

Early Rigid FOs

- Metal
 - Shaffer plates
 - Spring steel



Early Rigid FOs

- Leather
 - The original material used for "arch supports."
 - Shoemakers took sole leather and wet-molded it to casts.
 - Still used when patients want good support but cannot tolerate firmer plastics.
 - Bulky and heavy.



Early Rigid FOs

- Acrylics
 - Rohadur, Polydur, and Plexidur
 - Made from methyl methacrylate polymers.
 - Very prone to cracking.
 - Search for alternatives took on great urgency when it was discovered that the production process was carcinogenic.



Thermoplastics

- Commonly used thermoplastics
 - Homopolymer polypropylene
 - Copolymer polypropylene
 - High density polyethylene



Thermoplastics

- Polypropylene (homopolymer)
 - Economical material that offers a combination of outstanding physical, mechanical, thermal, and electrical properties not found in any other thermoplastic.
 - A plastic with a low specific gravity and high stiffness.
 - Good weight-to-strength ratio makes it ideal for manufacturing rigid foot orthotics.
 - Any notch or groove on the finished shell can create a stress point that may eventually crack.
 - Available in many colors and thicknesses.

Thermoplastics

- Polypropylene (copolymer)
 - Copolymer blend of polypro and polyethylene
 - PP >>> PE (typically 96:4)
 - A bit softer than HPP
 - Better impact strength, is tougher and more durable than HPP.
 - CPP tends to have better stress crack resistance and low temperature toughness than HPP.
 - Susceptible to “cold flow”.

Thermoplastics

- High density polyethylene (HDPE)
- Higher impact strength than PP.
- Inferior working temperature and tensile strength than PP.
- Subortholene™
 - Lightweight, strong, flexible, excellent stress crack resistance.
 - Molds well over deep heel cups and flanges.
 - Can be thinned without cracking.
 - Does not retain molded shape as well as PP.

Polycarbonates

Polycarbonates

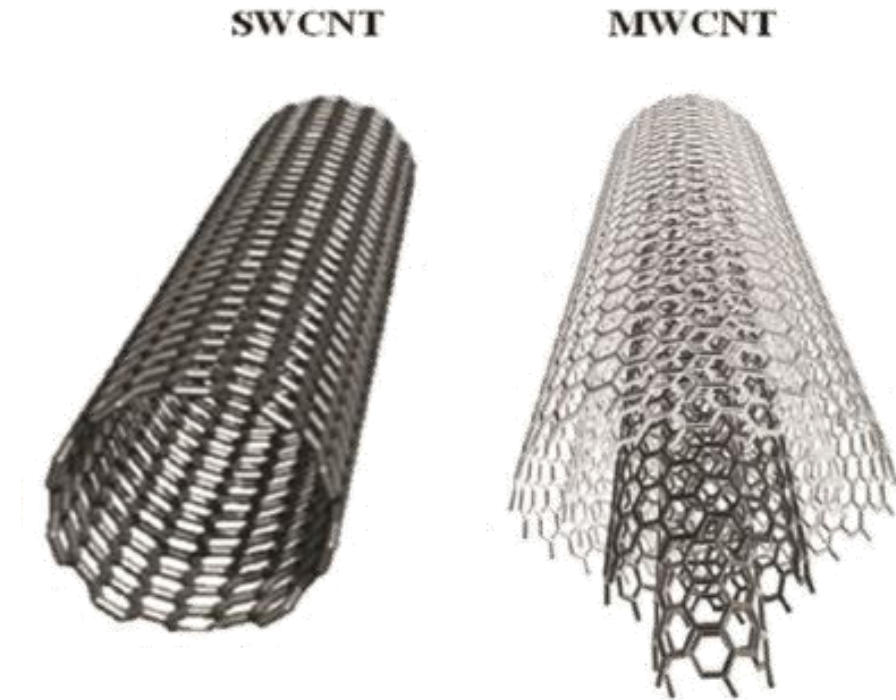
- Combining acrylic plastic with carbon fibers creates a rigid sheet material.
- Known by various trade names such as Exos[®], Carboplast, Graphite, and the TL-series.
- “Carbons” are good for thin, functional orthotics.
- They can be difficult to work with, requiring a higher softening temperature, faster vacuuming, and complete accuracy during the process as they cannot be “re-worked”.

Carbon Nanotubes

- What are CNT?
 - Discovered in 1991
 - CNT are at least 100 times stronger than steel, but only one-sixth as heavy, so nanotube fibers could strengthen almost any material.
 - Nanotubes can conduct heat and electricity far better than copper.
 - A carbon nanotube is a tube-shaped material, made of carbon, having a diameter measuring on the nanometer scale. (A nanometer is about 10,000 times smaller than a human hair.)
 - CNT are unique because the bonding between the atoms is very strong and the tubes can have extreme aspect ratios.
 - A carbon nanotube can be as thin as a few nanometers yet be as long as hundreds of microns. To put this into perspective, if your hair had the same aspect ratio, a single strand would be over 40 meters long.

Carbon Nanotubes

- A single-walled carbon nanotube is just like a regular straw.
- Multi-walled carbon nanotubes are a collection of nested tubes of continuously increasing diameters. They can range from one outer and one inner tube (a double-walled nanotube) to as many as 100 tubes or more.
- Each tube is held at a certain distance from either of its neighboring tubes by interatomic forces.



Carbon Nanotubes

- Currently, the most popular use for carbon nanotubes is in structural reinforcement. The high strength and low weight of CNT combined with their flexibility allow for them to be added to other materials like rebar to concrete.

Carbon Nanotubes

	Large-volume applications	Limited-volume applications	Key attributes
Present	Sporting goods such as golf shafts, tennis rackets, baseball bats etc., battery electrode additives, plastics additives and masterbatches, fuel line systems	Battery electrodes, boat hulls & decks, wind turbine blades, prepregs, scanning probe tips, sensors, catheters, membrane filters, flat panel displays, textiles, printing & packaging	Excellent mechanical and electrical conductivity properties, compatibility, high surface area ($\sim 1000 \text{ m}^2/\text{g}$), excellent chemical stability in acidic environments, distinguished optoelectronic properties, insensitivity to electromigration, excellent thermal conductivities and semiconducting properties
Near term (less than five years)	Supercapacitor electrodes, transparent conducting films, field emission displays, LCDs and OLED-based displays, fuel cell electrodes, inks for printing, adhesives	Electromechanical memory device, hydrogen-storage electrodes, biosensors, multitype array X-ray sources, probe array test systems, brush contacts, thermal-management systems	
Long term (beyond five years)	Power transmission cables, structural composites applications for aerospace and automobile, photovoltaic devices	Field-Effect Transistors (FET), interconnects, flexible electronics, drug-delivery systems	

Compare and Contrast

Polypropylene

- Polypropylene is an organic polymer made from propylene through a catalytic reaction.
- Good temperature resistance, good fatigue resistance, good chemical and environmental stress cracking resistance, good detergent resistance, high hardness, ease of processing by injection molding and extrusion are its properties.
- Less expensive
- Low impact strength

Polycarbonate

- Polycarbonate is a thermoplastic elastomer formed from the reaction between Bisphenol A and phosgene.
- Heat resistance, inherent flame retardance, ease of process, and clarity are properties of polycarbonate.
- More expensive
- High impact strength

Compare and Contrast

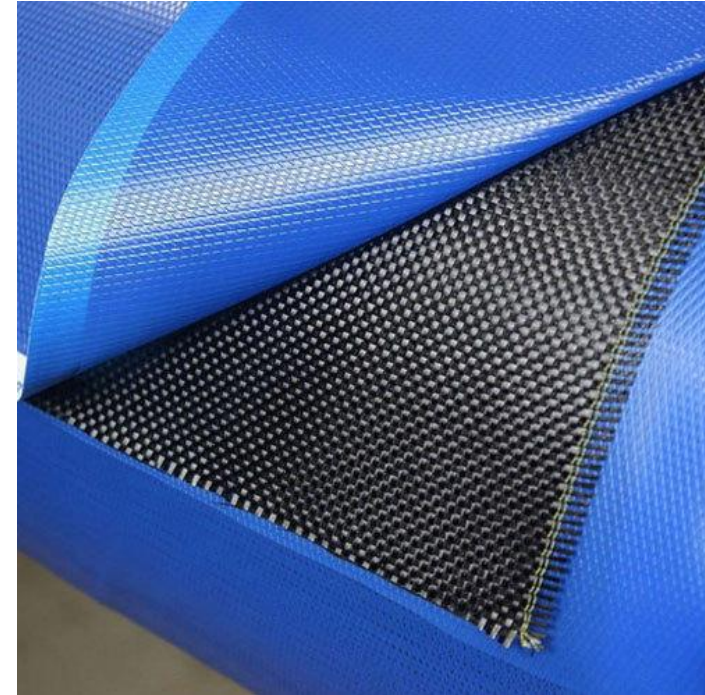
- Ductility and strength measured by a tensile test
- Fracture toughness = impact resistance

Typical Tensile Strength, Elongation, and Tensile Modulus of Polymers

Polymer Type	Ultimate Tensile Strength (MPa)	Elongation (%)	Tensile Modulus (GPa)
ABS	40	30	2.3
ABS + 30% Glass Fiber	60	2	9
Acetal Copolymer	60	45	2.7
Acetal Copolymer + 30% Glass Fiber	110	3	9.5
Acrylic	70	5	3.2
Nylon 6	70	90	1.8
Polyamide-Imide	110	6	4.5
Polycarbonate	70	100	2.6
Polyethylene, HDPE	15	500	0.8
Polyethylene Terephthalate (PET)	55	125	2.7
Polyimide	85	7	2.5
Polyimide + Glass Fiber	150	2	12
Polypropylene	40	100	1.9
Polystyrene	40	7	3

Carbon Composites Used in O,P&P

- Prepreg
 - Sheets of carbon fiber weave fabric preimpregnated with epoxy resin
 - Maximum strength properties
 - Variable strength and mechanical properties based on number and orientation of layers
 - Awesome strength-to-weight ratio
 - Pricey
 - Used in AFOs and prosthetic feet for dynamic energy return properties
 - Cannot be adjusted once formed



Carbon Composites Used in O,P&P

- TenCate Cetex® TL-2100
- Popular material in podiatry applications
- Continuous Fiber Reinforced Thermoplastic (CFRT®) composite laminate with carbon fiber and modified polymethylmethacrylate (PMMA) resin.
- Designed specifically for orthotics.
- Available in three four rigidities (thicknesses).
- Not adjustable once formed.

Carbon Composites Used in O,P&P

- Exos™
 - The patented Exos™ carbon nano-tube technology is a lightweight, low temperature thermoformable material allowing for quick, easy adjustments.
 - It's easy to form and bend to any curvature for deep heel cups and unusual arch shapes.
 - Reformable as many times as needed.
 - Available in 4 levels of rigidity.



Carbon Footplates

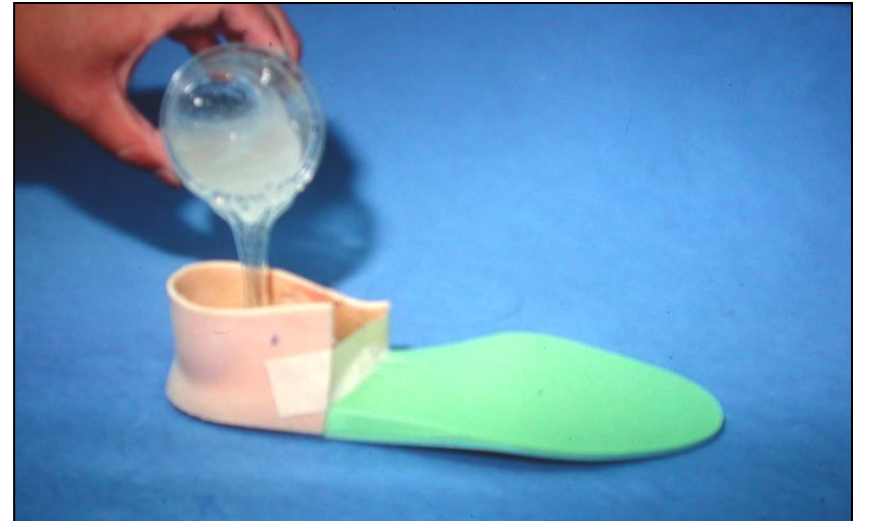
- Can be incorporated into a FO or used separately
- Alternative to extended steel shank in sole
- Different rigidities and configurations



Specialty Materials

Types of Materials

- Viscoelastic Polymers
 - Ex.
 - P.Q.[®], Viscolas[®], Silicone, Acton[®]
 - Not heat moldable
 - Some can be molded in liquid form
 - Durometer varies depending upon the mixture
 - Available in mixture kit or sheet stock
 - Cushion, cushion, cushion
 - Shock absorption / attenuation
 - Vibration isolation



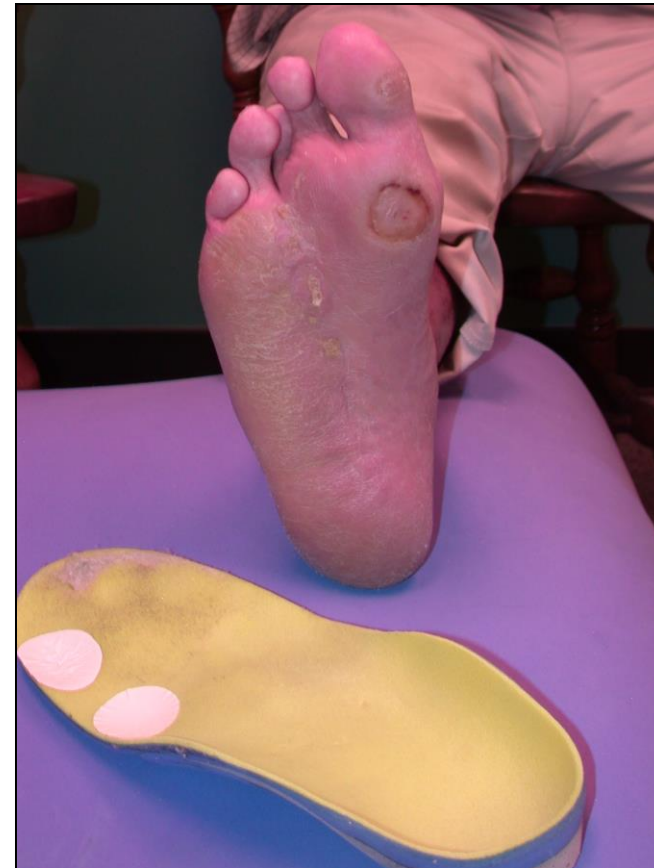
Viscoelastic Polymers

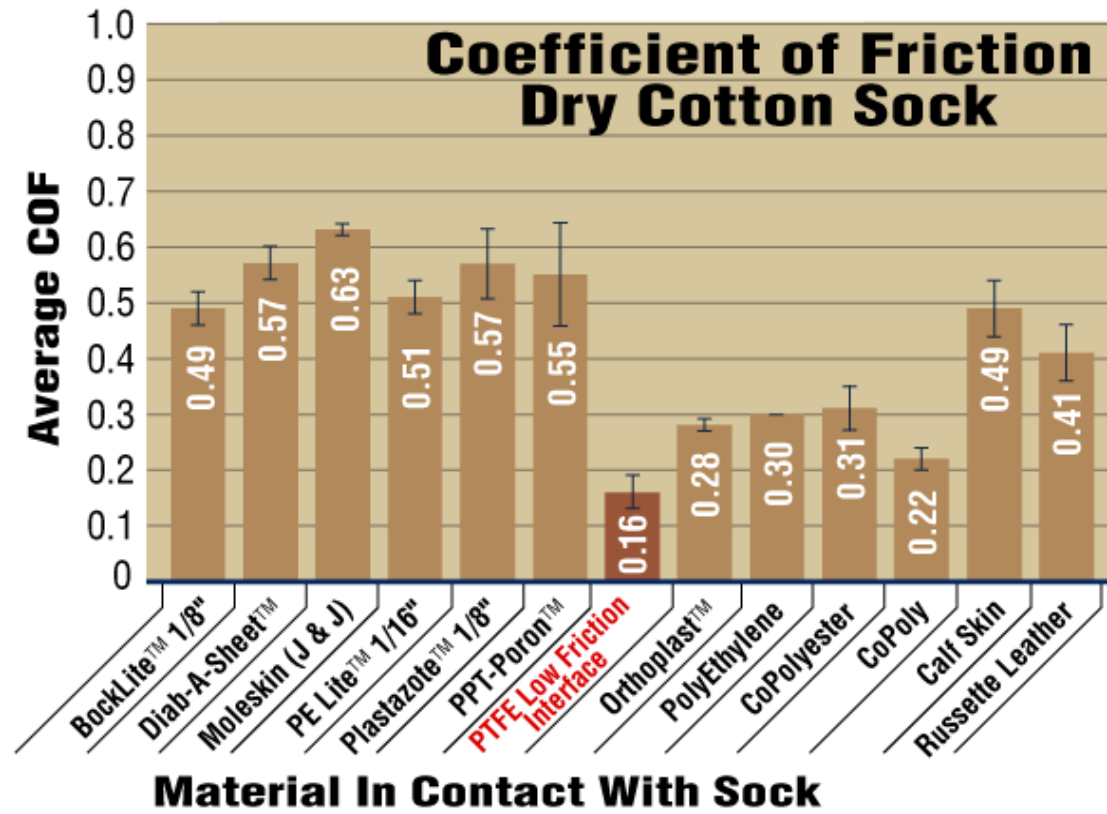
- Special applications
 - Replace atrophied or shifted plantar fat pads
 - Attenuate shock on heel strike (shin splints)
 - Fill void due to calcaneectomy
 - Tarsal tunnel syndrome



Types of Materials

- Low friction interface
 - Shear Ban



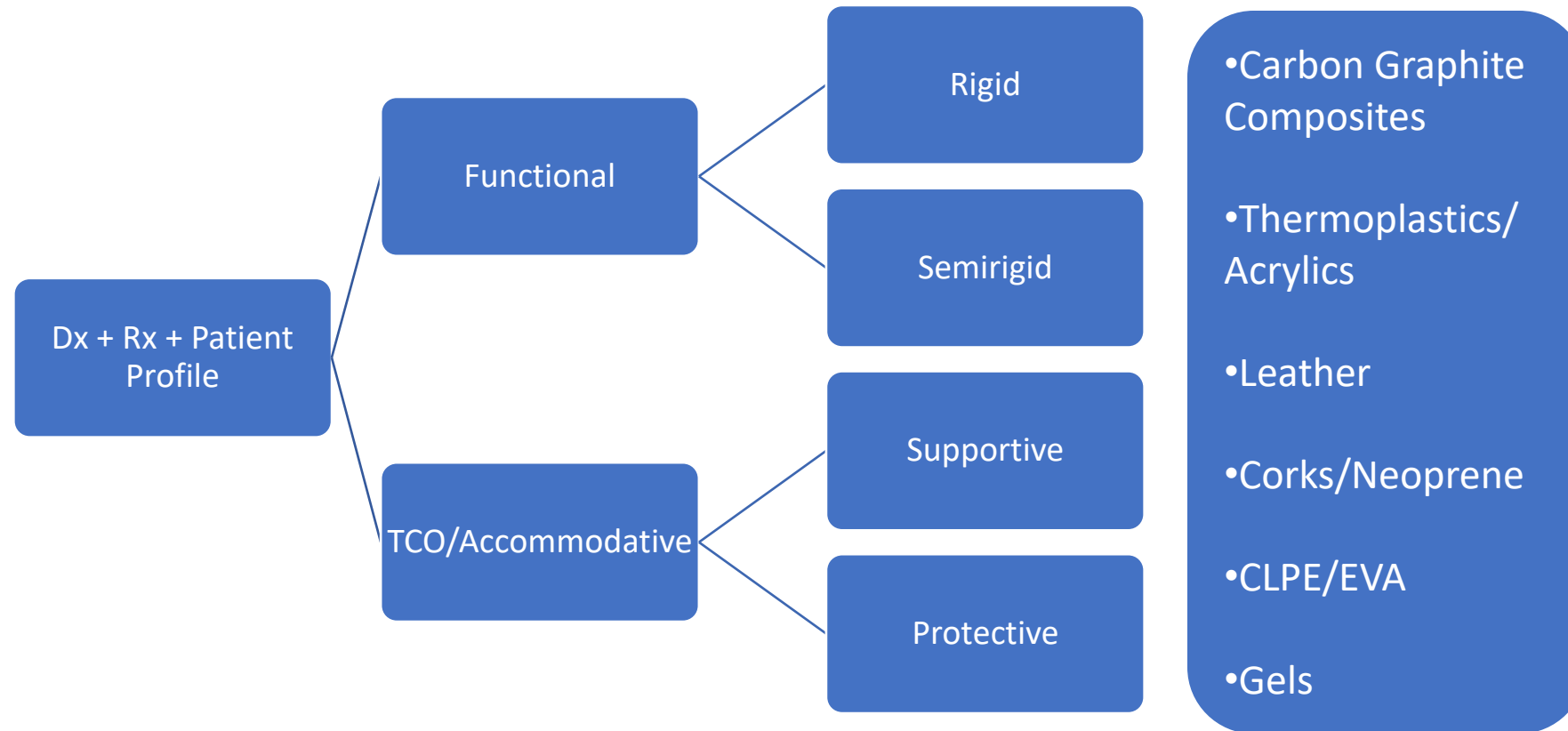


How to Decide...

How to Decide?

- Many different materials available
 - Each materials available in multiple thicknesses and densities
- Trade/brand names add to confusion
- Must balance:
 - Prescription
 - Diagnosis/Biomechanics
 - Patient Desires/Expectations
- Typically, material combinations are used

How to Decide

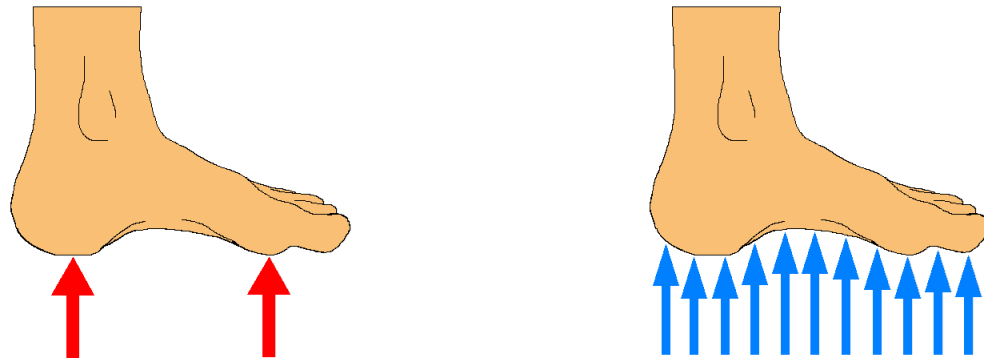


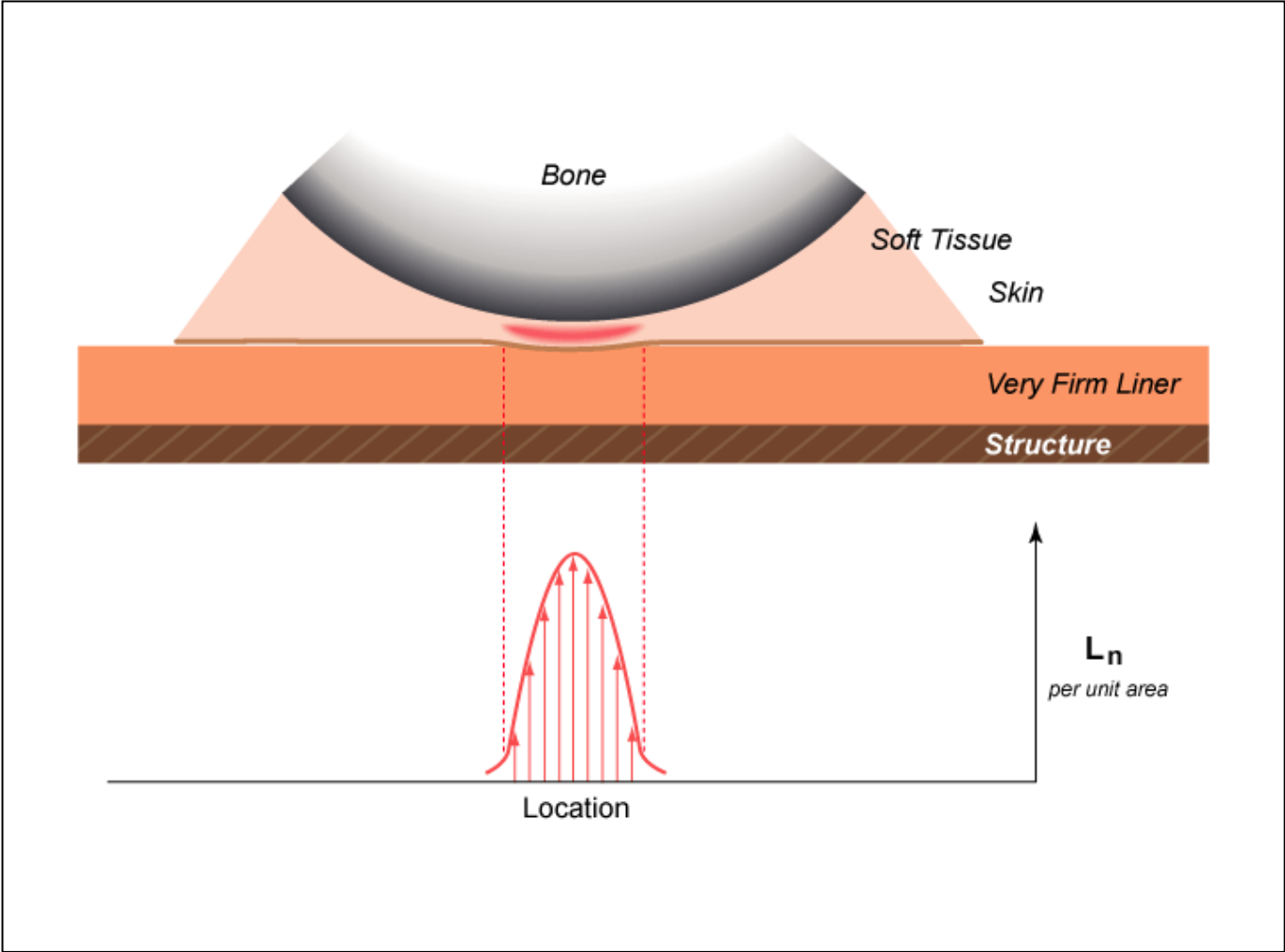
* Adapted from “Material Choices in Foot Orthotic Design” by Seamus Kennedy, BEng, CPed in O&PEdge 02/2008

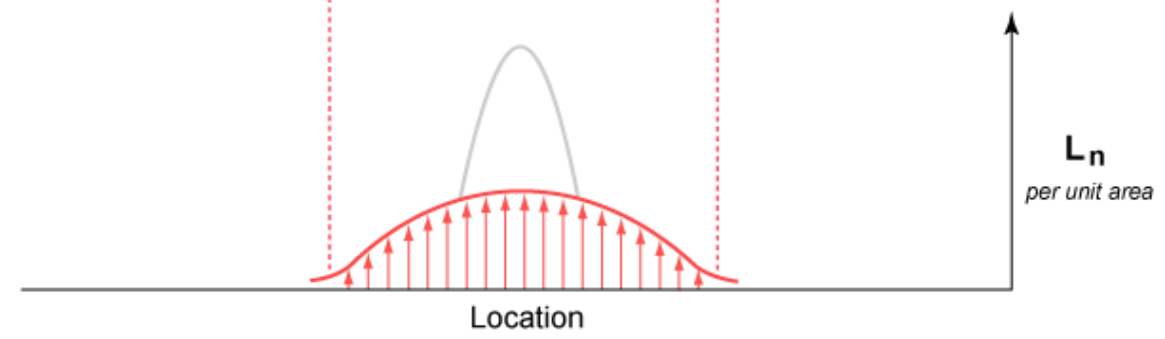
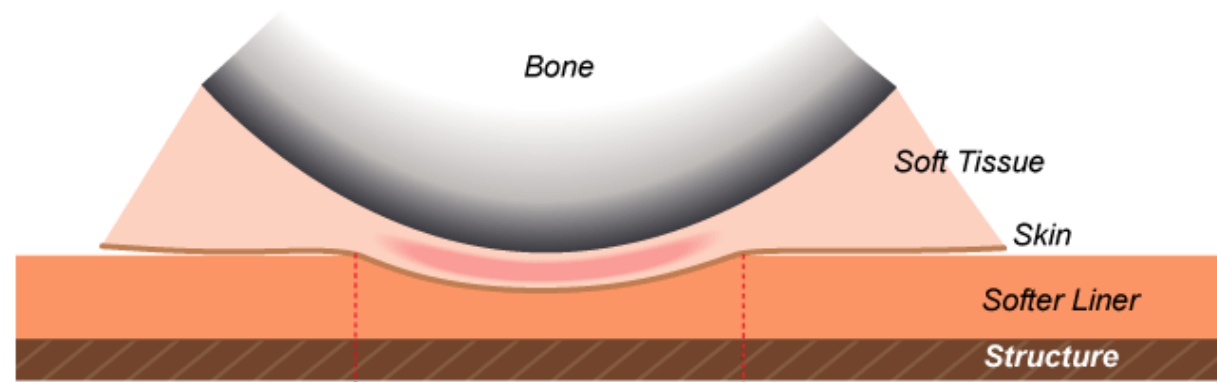
Objectives of Foot Orthotic Treatment

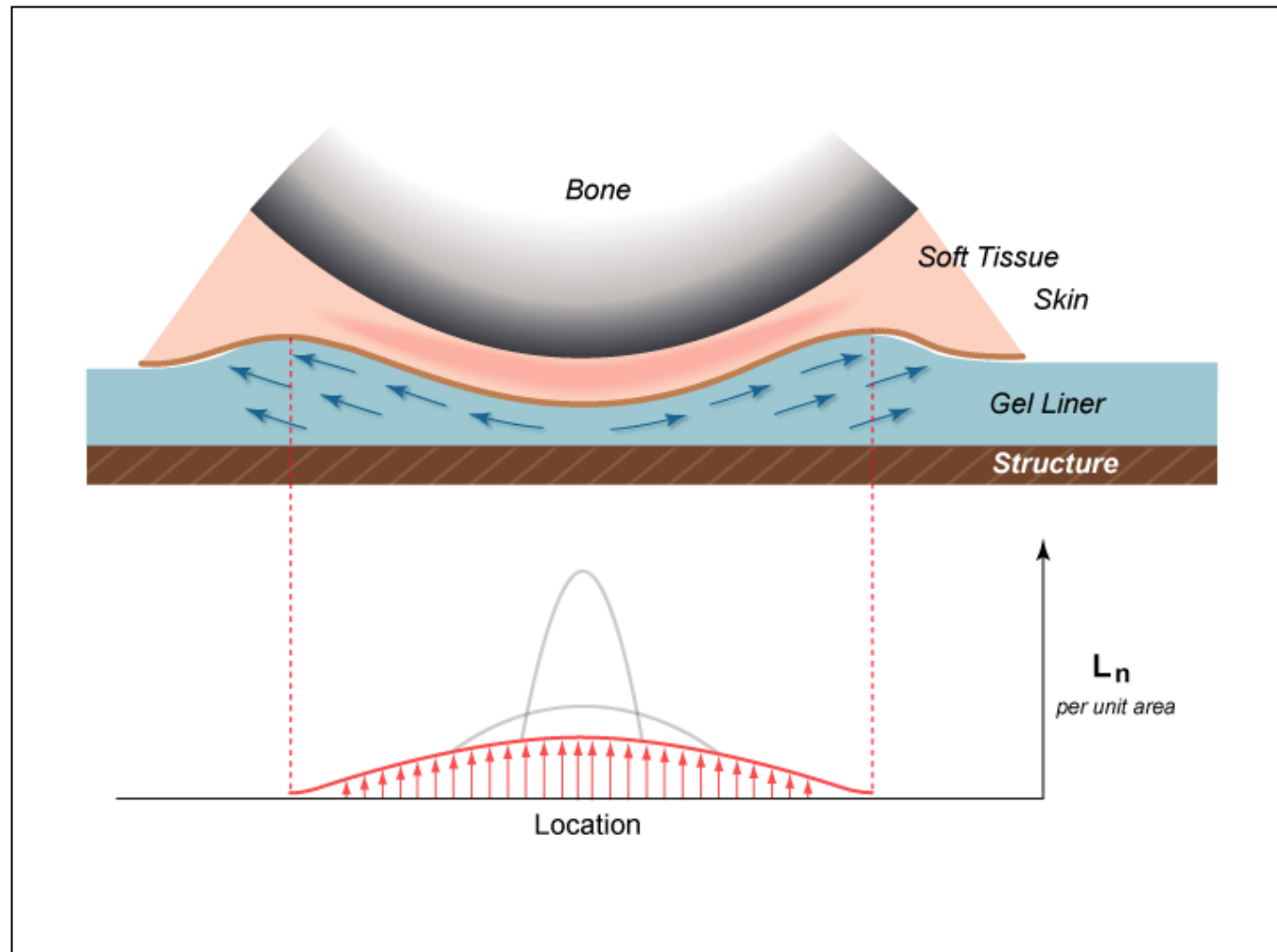
Foot Orthoses Objectives

- Redistribute weightbearing pressures more evenly
- Reduce peak pressures



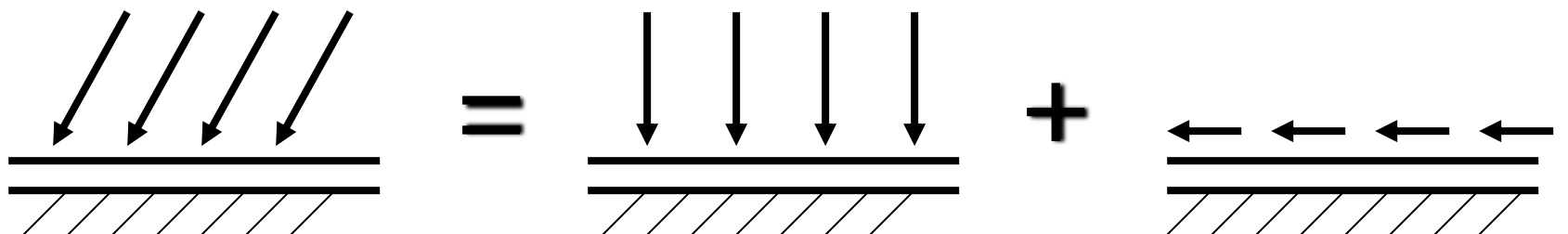






Foot Orthoses Objectives

- Redistribute weightbearing pressures more evenly
- Reduce peak pressures
- Reduce, control or restrict joint motion
- Reduce or restrict stress on soft tissue structures
- Reduce shear



Full Peak
Load,
 L

Perpendicular/
Normal Load
Component,
 L_n

Shear/Friction
Load
Component,
 L_f

Foot Orthoses Objectives

- The foot slides, twists and pistons inside the shoe...all of these motions cause shear
- Just as important as peak pressures when discussing repetitive loading and skin breakdown

Selection Considerations

- Type of disease, injury, deformity or disorder
- Foot structure and shape
- Age
- Weight
- Activity level
- Occupational, social or financial considerations
- Duration and type of pain

Selection Considerations

- Patient's history with foot orthoses and/or other treatment(s)
- Patient's current footwear
- Prescription
- Cost of materials Vs. Reimbursement

Material Characteristics

- Molding capabilities / Shape retention
- Adhesive qualities
- Ease of modification
- Support and/or rigidity
- Cushion
- Shock absorption / Shock attenuation
- Durability / Life expectancy of material

Types of Foot Orthoses

Types of Orthoses

- Accommodative
- Semi-rigid
- Rigid
- Partial Foot Prosthesis

Types of Orthoses

- Rigid Foot = Flexible Orthoses
- Flexible Foot = Rigid Orthoses
- Combinations often work best!

Types of Orthoses

- Accommodative – An orthosis fabricated with lower density materials designed specifically to protect, accommodate and cushion on the patient's foot
 - Primary materials used
 - Inner Shell: CL-PE, PU
 - Base: EVA



Types of Orthoses

- Accommodative – An orthosis fabricated with lower density materials designed specifically to protect, accommodate and cushion on the patient's foot
 - Pathologies treated
 - Diabetic conditions
 - Charcot deformities
 - Arthritic conditions
 - Amputations
 - Post-op
 - Post-fusion



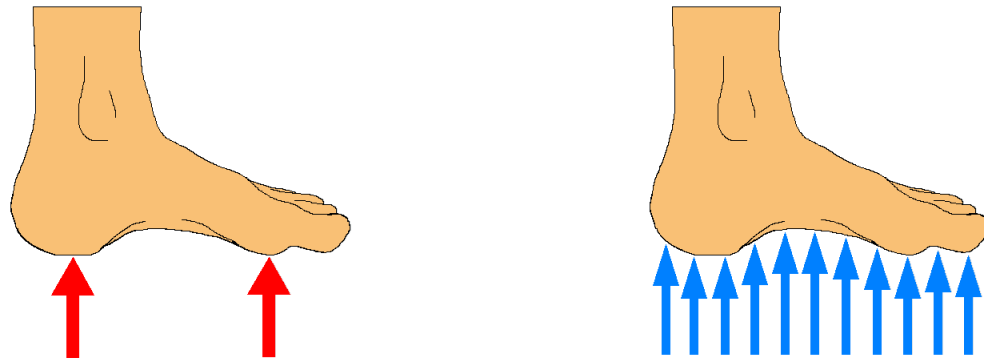
Types of Orthoses

- Semi-Rigid – An orthosis fabricated to provide additional support, balance, and control, and/or to reduce joint and tendon stress
 - Pathologies treated:
 - Metatarsalgia / sesamoiditis
 - Posterior tibial tendonitis
 - Some diabetic complications
 - Mid-foot RA
 - Plantar fasciitis
 - OA / DJD
 - Post-op



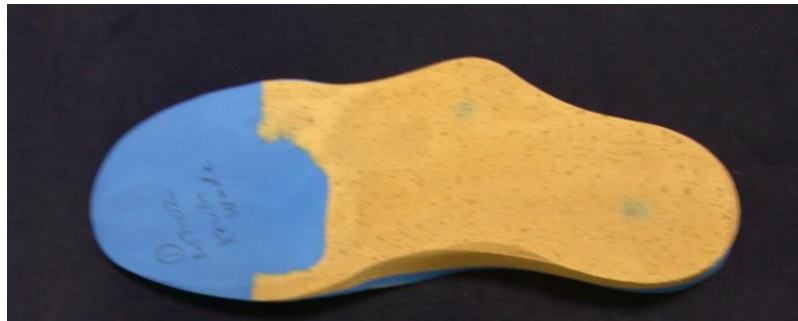
Concepts and Approaches

- Weight redistribution orthosis
 - Equalize pressures
 - Decrease pressure
 - Eliminate pressure
 - Support and control
 - Reduce shear



Types of Orthoses

- Semi-Rigid – An orthosis fabricated to provide additional support, balance, and control, and/or to reduce joint and tendon stress
 - Primary materials used: EVA's and Corks
 - CL-PE and PU can be used in certain cases
 - A high-density EVA or thin plastic can be used in certain cases



Types of Orthoses

- Rigid – An orthosis fabricated to maximize the level of control and/or support acquired below the ankle, reducing and/or eliminating joint tendon stress, and correcting flexible foot deformities
 - Pathologies treated:
 - Post-tibial tendon dysfunction
 - Hind foot and ankle arthritis / DJD
 - Plantar fasciitis
 - Flexible hind foot varus and valgus
 - Hind foot and ankle instability



Types of Orthoses

- Rigid – An orthosis fabricated to maximize the level of control and/or support acquired below the ankle, reducing and/or eliminating joint tendon stress, and correcting flexible foot deformities
 - Primary materials used:
 - Copolymer, polypropylene, subortholene, carbon fiber composites

Partial Foot Prosthesis

- Protect residual foot
- Maintain position in shoe
- Redistribute WB pressures



Partial Foot Prosthesis

Necessary to replace lost lever arm

- ESS
- Carbon fiber plate
- Turf Toe Plate
- Stiff Soled-shoe

Necessary to replace lost motion

- Rocker soles



Posting/Relief Methods

Intrinsic

Vs.

Extrinsic

Posting/Relief Methods

- **Intrinsic** - Built into positive model
- **Pros:**
 - Aesthetically pleasing
- **Cons:**
 - Requires exact precision
 - Not easily adjusted

Posting/Relief Methods

- Intrinsic
 - Types of relief
 - Metatarsal pad
 - Relief for prominence
 - Wedging



Posting/Relief Methods

- Extrinsic - Added to finished orthosis
- Pros:
 - Very adjustable
 - More applications than intrinsic
- Cons:
 - ?



Posting/Relief Methods

- Extrinsic
 - Types of relief
 - Metatarsal pad
 - Global met. head relief
 - Specific met. head relief
 - Morton's extension
 - Relief for prominence
 - Wedging
 - Heel lift



Fabrication Methods

Fabrication Techniques Comparison

- What is the difference between “molded” FOs and “milled” FOs?
- HPP, CPP and HDPE can be molded or milled.
- Polycarbonates like Exos™ must be molded.

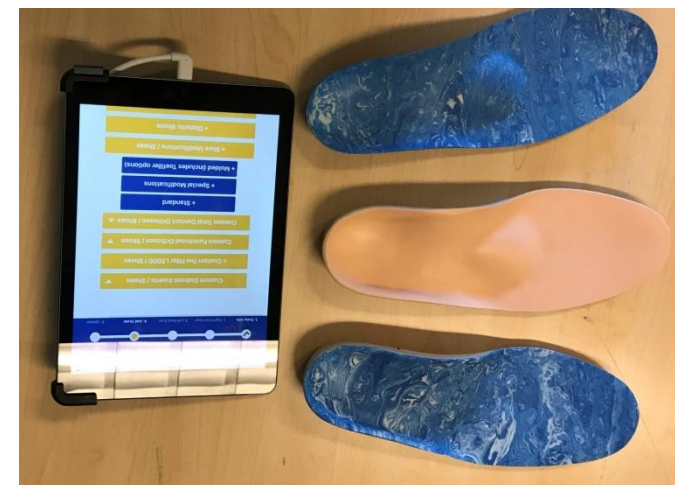
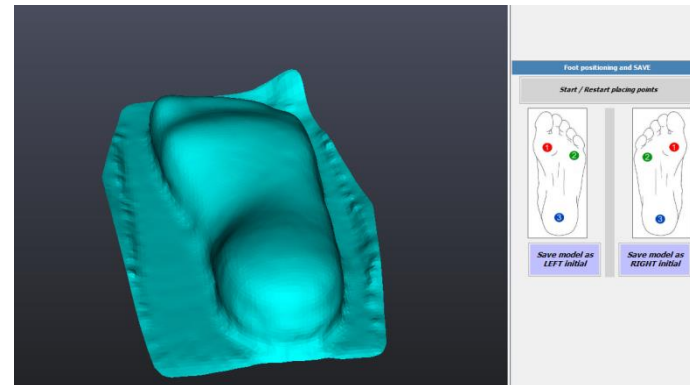
Milling/CNC

- Pros
 - Most efficient method*
 - Infinitely more repeatable than vacuum-forming
 - Ease of adding intrinsic relief/posting
- Cons
 - Learning curve for design software
 - CAD/set-up time
 - Equipment is more expensive



*30 prs/hr

Milled



Traditional Vacuum Forming

- Pros
 - Ability to mold deep heel cups and high flanges
 - More options in material selection
 - No anxiety about having to move into the 21st Century
 - Plenty of time for smoke breaks
- Cons
 - Inefficient
 - Labor intensive
 - Expensive



Molded



3-D Printing

- Pros

- Limitless design capabilities
- Locally variable density
- Technology constantly expanding and improving

- Cons

- Growing, but limited selection of materials
- Initial equipment expenses
- CAD/set-up time
- Comparatively sloooooow...



- **The biomechanical effects of 3D printed and traditionally made foot orthoses in individuals with unilateral plantar fasciopathy and flat feet**
 - Ho M, Nguyen J, Heales L, Stanton R, Kong PW, Kean C. The biomechanical effects of 3D printed and traditionally made foot orthoses in individuals with unilateral plantar fasciopathy and flat feet. *Gait Posture*. 2022 Jul;96:257-264. doi: 10.1016/j.gaitpost.2022.06.006. Epub 2022 Jun 11. PMID: 35709609.
- **Research question:** How effective are 3D-printed FOs (3D-Print) compared to traditionally-made (Traditional) or no FOs (Control), in changing biomechanical parameters of flat-footed individuals with unilateral plantar fasciopathy?
- **Methods:** Thirteen participants with unilateral plantar fasciopathy walked with shoes under three conditions: Control, 3D-print, and Traditional. 2×3 repeated measures analysis of variance (ANOVAs) with Bonferroni post-hoc tests were used to compare discrete kinematic and kinetic variables between limbs and conditions. Waveform analyses were also conducted using statistical parametric mapping (SPM).
- **Results:** There was a significant condition main effect for arch height drop ($p = 0.01$; $\eta p^2 = 0.54$). There was 0.87 mm (95% CI [-1.84, -0.20]) less arch height drop in 3D-print compared to Traditional. The SPM analyses revealed condition main effects on ankle moment ($p < 0.001$) and ankle power ($p < 0.001$). There were significant differences between control condition and both 3D-print and Traditional conditions. For ankle moment and power, there were no differences between 3D-print and Traditional conditions.
- **Significance:** 3D-printed FOs are more effective in reducing arch height drop, whilst both FOs lowered ankle plantarflexion moment and power compared to no FOs. The results support the use of 3D-printed FOs as being equally effective as traditionally-made FOs in changing lower limb biomechanics for a population of flat-footed individuals with unilateral plantar fasciopathy.

- **Novel 3D-printed foot orthoses with variable hardness: A comfort comparison to traditional orthoses**

- Walker KJ, Przestrzelski BT, Kaluf B, Driggers NH, Ballard WD 2nd, Pruett TC, Hoeffner SL, DesJardins JD. Novel 3D-printed foot orthoses with variable hardness: A comfort comparison to traditional orthoses. Med Eng Phys. 2023 May;115:103978. doi: 10.1016/j.medengphy.2023.103978. Epub 2023 Apr 7. PMID: 37120178.
- Both the 3D-printed and the traditionally fabricated foot orthoses demonstrated statistically significant increases in comfort when compared to the factory fabricated shoe insert. Additionally, the two orthosis groups were not significantly different from each other in comfort rankings both regionally and overall, at any time point. The similar comfort achieved by the 3D-printed orthosis to the traditionally fabricated orthosis after 7 days and 14 days emphasizes the potential of the future use of the more reproducible and adaptable 3D-printed orthosis manufacturing methodology.

Issue with many FO studies...

- **Construction and validation of sham insoles used in clinical trials: A systematic review**
 - Morrow EM, Theologis T, Kothari A. Construction and validation of sham insoles used in clinical trials: A systematic review. Prosthet Orthot Int. 2022 Apr 1;46(2):121-133. doi: 10.1097/PXR.0000000000000091. PMID: 35019884.
- **Background:** Insoles are commonly prescribed to treat pathologies in a variety of patient groups; however, there is limited evidence to guide clinical decision-making. A well-validated sham insole is critical to conducting a double-blind placebo-controlled trial.
- **Objectives:** The aims were to establish: (1) How are sham insoles constructed? (2) What measures are undertaken to ensure adequate blinding? (3) What methods are used to validate the biomechanical effects?
- **Methods:** Searches were conducted in MEDLINE, Embase, Cumulative Index of Nursing and Allied Health Literature, and Cochrane Central Register of Controlled Trials. Inclusion criteria were placebo-controlled clinical trials, sham insoles used, treatment insoles alter biomechanics, treatment insoles meet the ISO definition of foot orthotics, sham and treatment insoles tested in normal walking, and article available in English.
- **Results:** The search generated 270 results. Twenty-four trials were included. 19% of sham insoles were described sufficiently to be replicated. The most common sham construction characteristics were full length, ethylene-vinyl acetate material, and flat insoles. 58% of studies were double-blinded; however, many did not describe any blinding methods. There is evidence that blinding the intervention details and a similar insole appearance is effective to blind participants. 13% of studies included a shoe-only condition to allow assessment of the biomechanical effects of sham insoles.
- **Conclusions:** There is inconsistent construction, blinding, and biomechanical validation of sham insoles. This casts a substantial doubt on the quality and reliability of the evidence base to support the prescription of insoles.

Problems

- We know it works...but why don't the studies agree?
- How many CPeds are involved in the studies?
- Are the studies only done by academics?
- Are adjustments allowed?
- What are the “sham” orthotics?
- Pedorthics is more of an art than a science.
- Metrics involved are often quite subjective

What's the Best?

- Sometimes the “Best” foot orthosis is:
 - What was already working for the patient
 - What the physician specifically ordered
 - Orthosis you've had the best track record with for this condition
 - Capture technique you're most comfortable with
 - The one the patient can afford

Leather Uppers

Calfskin—hides of calves; fine grain, soft, pliable, withstands hard wear (scuffing)

Kidskin—hides of goats; lightweight, yet strong and resilient.

Deerskin—hides of deer; soft and flexible; *not* durable - subject to holes and scarring

Pigskin—skins of pigs; used as sueded or brushed leather; often used in shoe linings.

Tanning-process of converting raw hides and skins into leather.

Shoe Materials

Non-leather Uppers

Lycra® - Stretchy, breathable material perfect for accommodating forefoot deformities like bunions and claw toes

Wool – Lightweight, washable, soft, breathable and odor resistant

Canvas - Breathable, stretchable and durable

Printed PU - Breathable and fashionable

Mesh fabric – Breathable, soft material good for athletic shoes



Manmade: Vinyls and urethanes are common; sometimes used to make shoe uppers; lower in cost, low maintenance; inability to breathe and no memory retention.



Soles

- Rubber
- EVA
- Neoprene
- Leather



(Covered much more extensively in “Shoe Manufacture and Construction”)

Conclusion

- A great many factors go into determining what combination of material will work best for a given patient.
- And...combinations *do* work best!
- Many manufacturers have the same, or very similar, materials with different names.
- Keep in mind that manufacturing a material to a very precise durometer reading is not easy (and rarely seen).
- The best orthosis is the one that works.

The End