# Foot biomechanics in diabetes and off loading strategies

*Professor Chris Nester, University of Salford, UK*

https://twitter.com/ProfChrisNester

# Funding & Colleagues & Declarations


**SSHOES**

**Special Shoes Movement**

**NMP-2008-SME-2-R.229261**

**SMARTPIF**

**SMART TOOLS for the Prescription of INSOLES and FOOTWEAR**

***SME GA n. 312573***

Deutsche Sporthochschule Köln
German Sport University Cologne


**Declaration:**
Nester and University of Salford have a commercial interest in an orthotics company (Salfordinsole) that was a partner in **SMARTPIF** project

# IWGDF Guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes

*Prepared by the IWGDF Working Group on Footwear and Offloading*



## Casting and prefabricated healing devices

**Are casting or prefabricated offloading effective techniques to heal plantar foot ulcers in patients with diabetes?**

*Recommendation 1:*
To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot-device interface.
(GRADE recommendation: strong, Quality of evidence: high)

*Rationale 1:*
Two high-quality systematic reviews and meta-analyses of randomized and non-randomized controlled trials indicate that the use of non-removable offloading devices (both TCC and walkers rendered irremovable) results in a significantly higher proportion of healed diabetic neuropathic plantar forefoot ulcers when compared to removable off-loading devices (including both walkers and footwear).[12,13] A Cochrane systematic review and meta-analysis included five RCTs[14-18] with a cumulative total of 230 patients and found a relative risk ratio of 1.17 (95%CI 1.01-1.36; p=0.04) for non-removable offloading to achieve healing compared to removable offloading.[12] Another systematic review and meta-analysis included 10 randomized and non-randomized clinical studies with a cumulative total of 524 patients[14-18,16-24] and showed a significantly higher relative risk ratio of 1.43 (95%CI 1.11-1.84, p=0.001) for non-removable offloading to achieve healing compared to removable offloading.[13] Based on two, relatively small RCTs,[17,25] there is evidence to suggest that a removable walker rendered irremovable is as effective as a TCC in healing neuropathic plantar forefoot ulcers (RR=1.06; 95%CI 0.88-1.27; p=0.31).[13] Therefore, there is no particular preference for a TCC or prefabricated non-removable knee-high device to heal plantar foot ulcers, as long as an appropriate foot device interface is maintained. We conclude that the quality of evidence is high.

Possible adverse effects of non-removable knee-high devices include ankle joint immobilization, reduced activity level, potential risk of falls, knee or hip complaints due to asymmetry in walking from the unilaterally increased sole height, and pressure ulcers due to poor casting or fitting.[15,26,27] Nevertheless, we consider the benefits of effective and expedited healing to outweigh such potential harm. Many patients may prefer not to use a non-removable knee-high device as it limits them in their daily life, for example with sleeping, bathing, or driving a

## Objective

- Example off loading strategies (there are others!)
- Biomechanics led design (evidence led design)
- Focus on getting optimised solutions for individual patients (targeted)

***++ Focus on prevention***

# Assumption

"*there is something different about the foot of each patient that I need to understand and use to build my orthotic prescription, if I don't it will affect the outcome*".

# Assumption

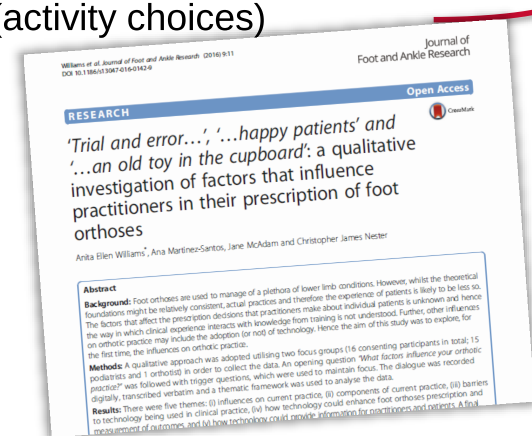
**“***there is something different about the foot of each patient that I need to understand and use to build my orthotic prescription, if I don’t it will affect the outcome*”.

- ✓ **FOOT SHAPE** (foot type or deformity)
- ✓ **TISSUE** (thickness, stiffness, position, quality)
- ✓ **ACTIVITY** (low or high levels)
- ✓ **MOBILITY** (stiff to compliant foot)
- ✓ **FOOTWEAR** (activity choices)

Integrate with experience

Set objectives for the orthotic (or footwear)

identify orthotic design features (shapes, materials) that might meet these objectives…but it is **“trial and error”**



Williams et al. Journal of Foot and Ankle Research (2016) 9:11
DOI 10.1186/s13047-016-0142-9

Journal of Foot and Ankle Research

RESEARCH — Open Access

*‘Trial and error…’, ‘…happy patients’ and ‘…an old toy in the cupboard’*: a qualitative investigation of factors that influence practitioners in their prescription of foot orthoses

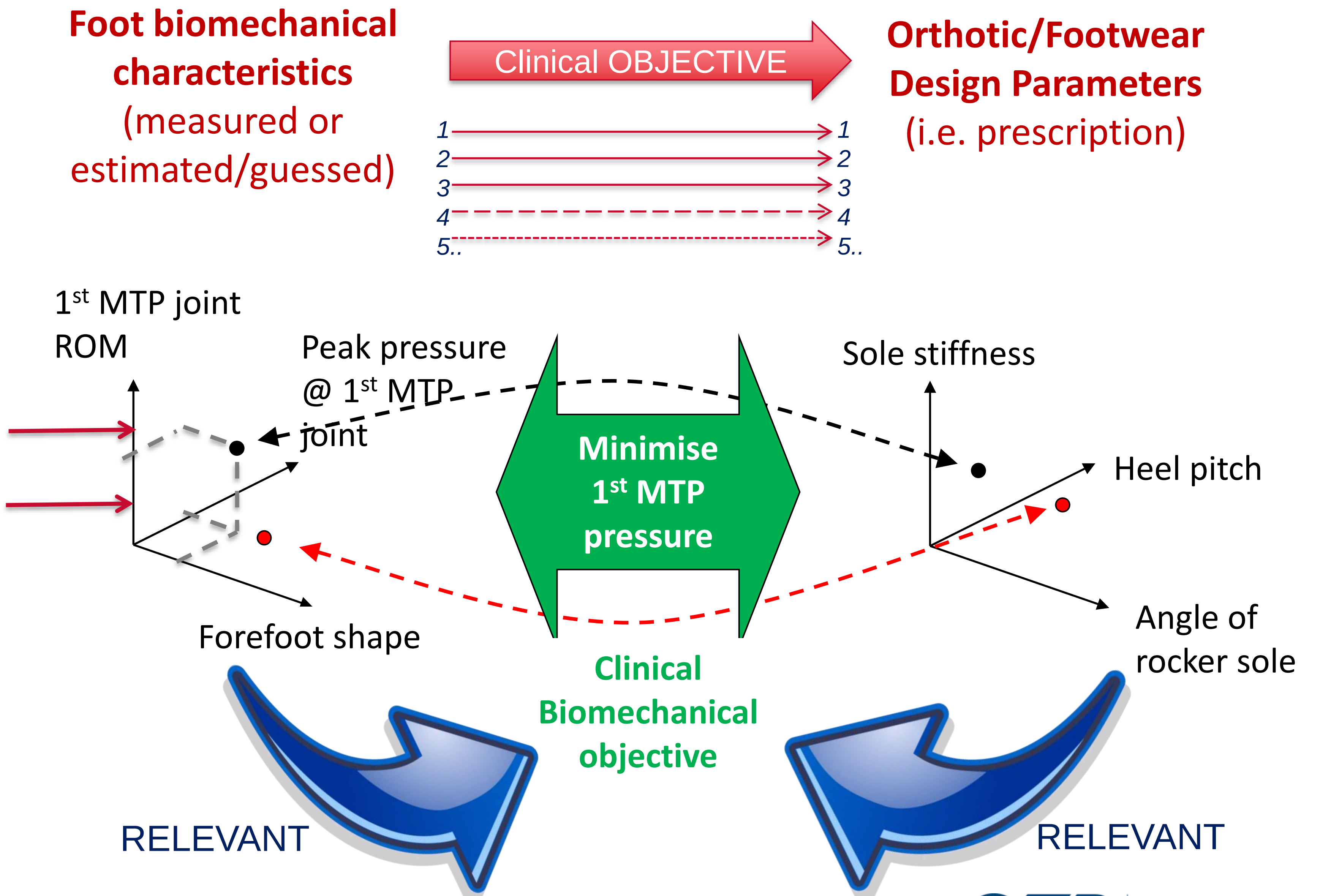
Anita Ellen Williams*, Ana Martinez-Santos, Jane McAdam and Christopher James Nester

**Abstract**

**Background:** Foot orthoses are used to manage of a plethora of lower limb conditions. However, whilst the theoretical foundations might be relatively consistent, actual practices and therefore the experience of patients is likely to be less so. The factors that affect the prescription decisions that practitioners make about individual patients is unknown and hence the way in which clinical experience interacts with knowledge from training is not understood. Further, other influences on orthotic practice may include the adoption (or not) of technology. Hence the aim of this study was to explore, for the first time, the influences on orthotic practice.

**Methods:** A qualitative approach was adopted utilising two focus groups (16 consenting participants in total; 15 podiatrists and 1 orthotist) in order to collect the data. An opening question *‘What factors influence your orthotic practice?’* was followed with trigger questions, which were used to maintain focus. The dialogue was recorded digitally, transcribed verbatim and a thematic framework was used to analyse the data.

**Results:** There were five themes: (i) influences on current practice, (ii) components of current practice, (iii) barriers to technology being used in clinical practice, (iv) how technology could enhance foot orthoses prescription and




Ortopedtekniska Branschrådet

**Foot biomechanical characteristics**
(measured or estimated/guessed)

Clinical OBJECTIVE

1 → 1
2 → 2
3 → 3
4 → 4
5.. → 5..

**Orthotic/Footwear Design Parameters**
(i.e. prescription)

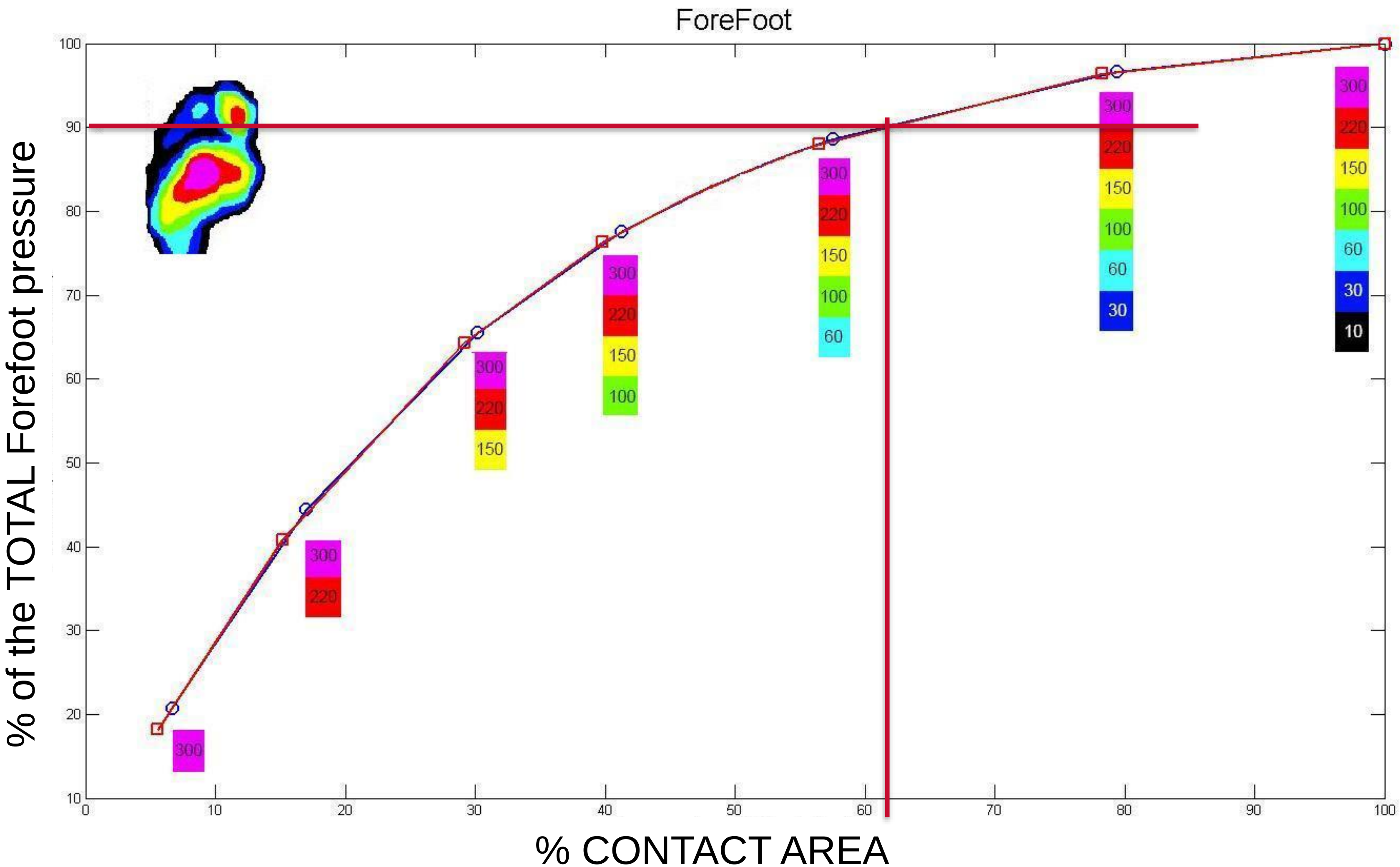
For a given set of **FOOT biomechanical characteristics**, there are a set of optimal **orthotic/footwear design parameters** which can be used to achieve a **specific clinical biomechanical objective**

## ENPODHE 2018

The University of Salford is proud to host the 7th ENPODHE conference **March 21-23rd 2018.**


**Dr Sicco Bus**
“Evidence based approach to off loading the diabetic foot?”

**International Working Group on the Diabetic Foot.** http://iwgdf.org/



ForeFoot
% of the TOTAL Forefoot pressure
% CONTACT AREA
100
90
80
70
60
50
40
30
20
10
0
10
20
30
40
50
60
70
80
90
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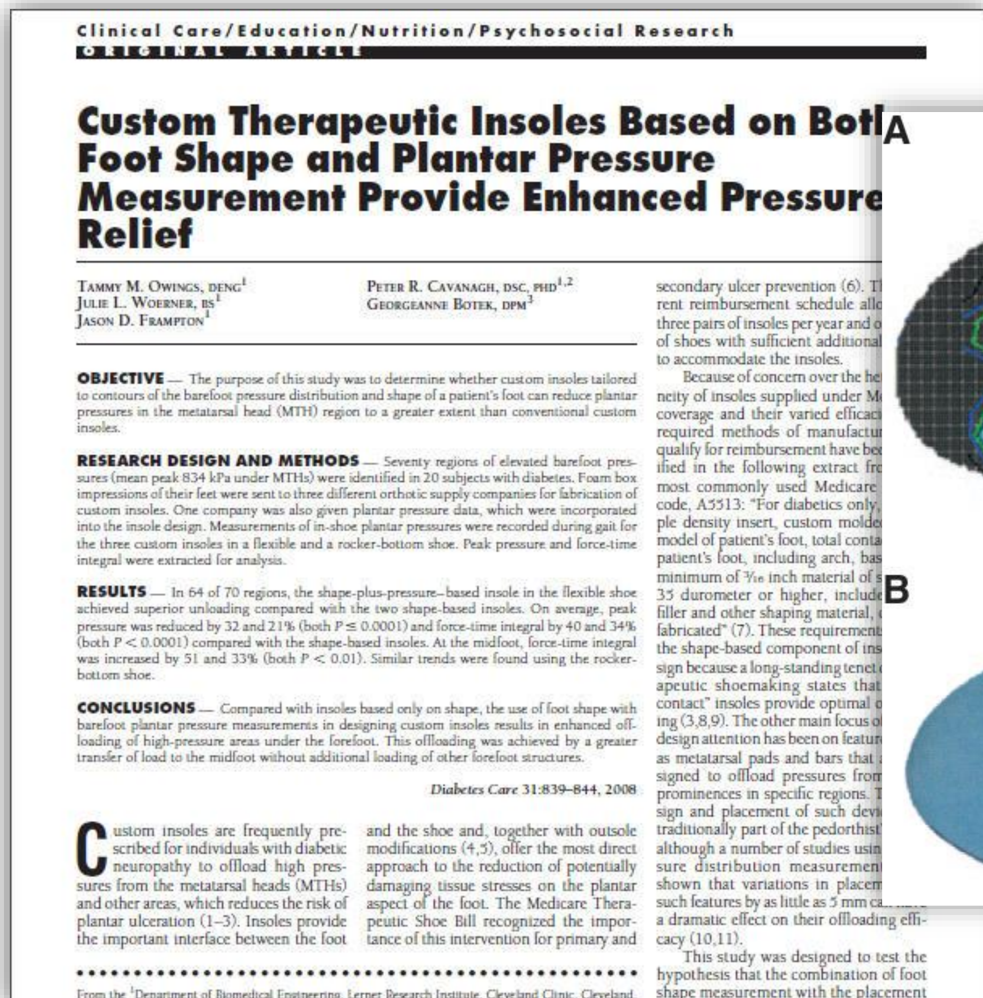
300
220
150
100
60
30
10

# Orthotic example



Clinical Care/Education/Nutrition/Psychosocial Research

ORIGINAL ARTICLE

## Custom Therapeutic Insoles Based on Both Foot Shape and Plantar Pressure Measurement Provide Enhanced Pressure Relief


Tammy M. Owings, DEng[1]
Julie L. Woerner, BS[1]
Jason D. Frampton[1]
Peter R. Cavanagh, DSc, PhD[1,2]
Georgeanne Botek, DPM[3]



**OBJECTIVE** — The purpose of this study was to determine whether custom insoles tailored to contours of the barefoot pressure distribution and shape of a patient's foot can reduce plantar pressures in the metatarsal head (MTH) region to a greater extent than conventional custom insoles.

**RESEARCH DESIGN AND METHODS** — Seventy regions of elevated barefoot pressures (mean peak 834 kPa under MTHs) were identified in 20 subjects with diabetes. Foam box impressions of their feet were sent to three different orthotic supply companies for fabrication of custom insoles. One company was also given plantar pressure data, which were incorporated into the insole design. Measurements of in-shoe plantar pressures were recorded during gait for the three custom insoles in a flexible and a rocker-bottom shoe. Peak pressure and force-time integral were extracted for analysis.

**RESULTS** — In 64 of 70 regions, the shape-plus-pressure–based insole in the flexible shoe achieved superior unloading compared with the two shape-based insoles. On average, peak pressure was reduced by 32 and 21% (both $P \leq 0.0001$) and force-time integral by 40 and 34% (both $P < 0.0001$) compared with the shape-based insoles. At the midfoot, force-time integral was increased by 51 and 33% (both $P < 0.01$). Similar trends were found using the rocker-bottom shoe.

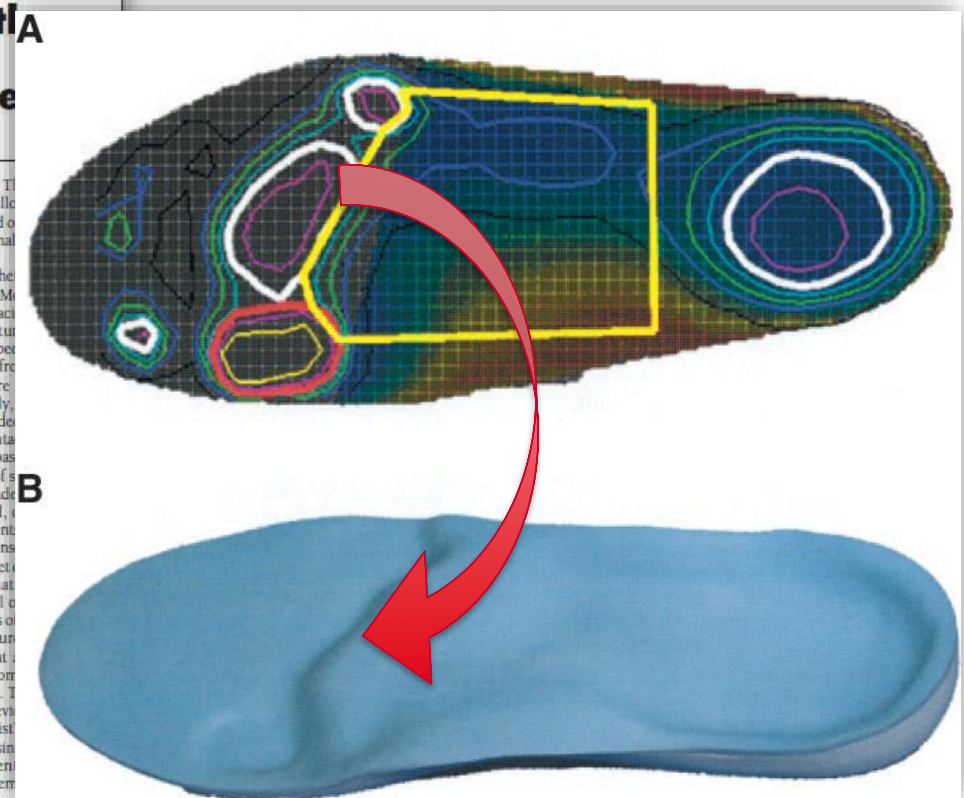
**CONCLUSIONS** — Compared with insoles based only on shape, the use of foot shape with barefoot plantar pressure measurements in designing custom insoles results in enhanced offloading of high-pressure areas under the forefoot. This offloading was achieved by a greater transfer of load to the midfoot without additional loading of other forefoot structures.



*Diabetes Care* 31:839–844, 2008


Custom insoles are frequently prescribed for individuals with diabetic neuropathy to offload high pressures from the metatarsal heads (MTHs) and other areas, which reduces the risk of plantar ulceration (1–3). Insoles provide the important interface between the foot and the shoe and, together with outsole modifications (4,5), offer the most direct approach to the reduction of potentially damaging tissue stresses on the plantar aspect of the foot. The Medicare Therapeutic Shoe Bill recognized the importance of this intervention for primary and


From the [1]Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic, Cleveland,


Owings et al 2008

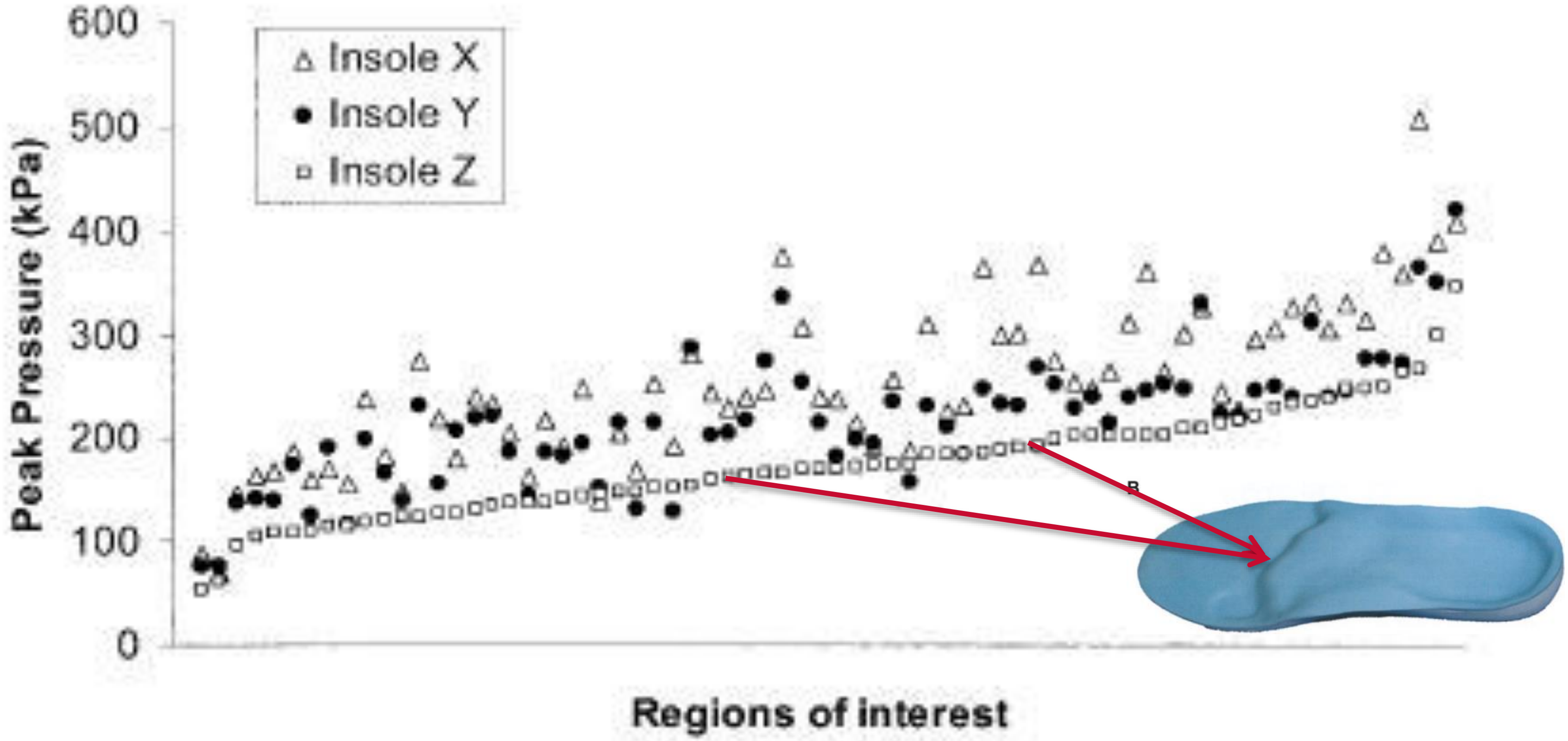



**Figure 2**—*Individual peak pressures (ranked by peak pressure of insole Z) at 70 ROIs for insoles in flexible shoes. △, insole X; ●, insole Y; □, insole Z.*

Ortopedtekniska
Branschrådet

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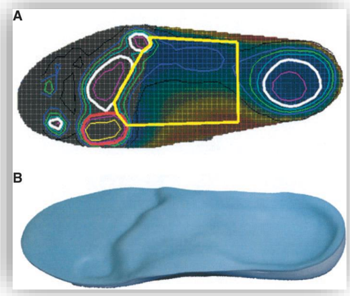
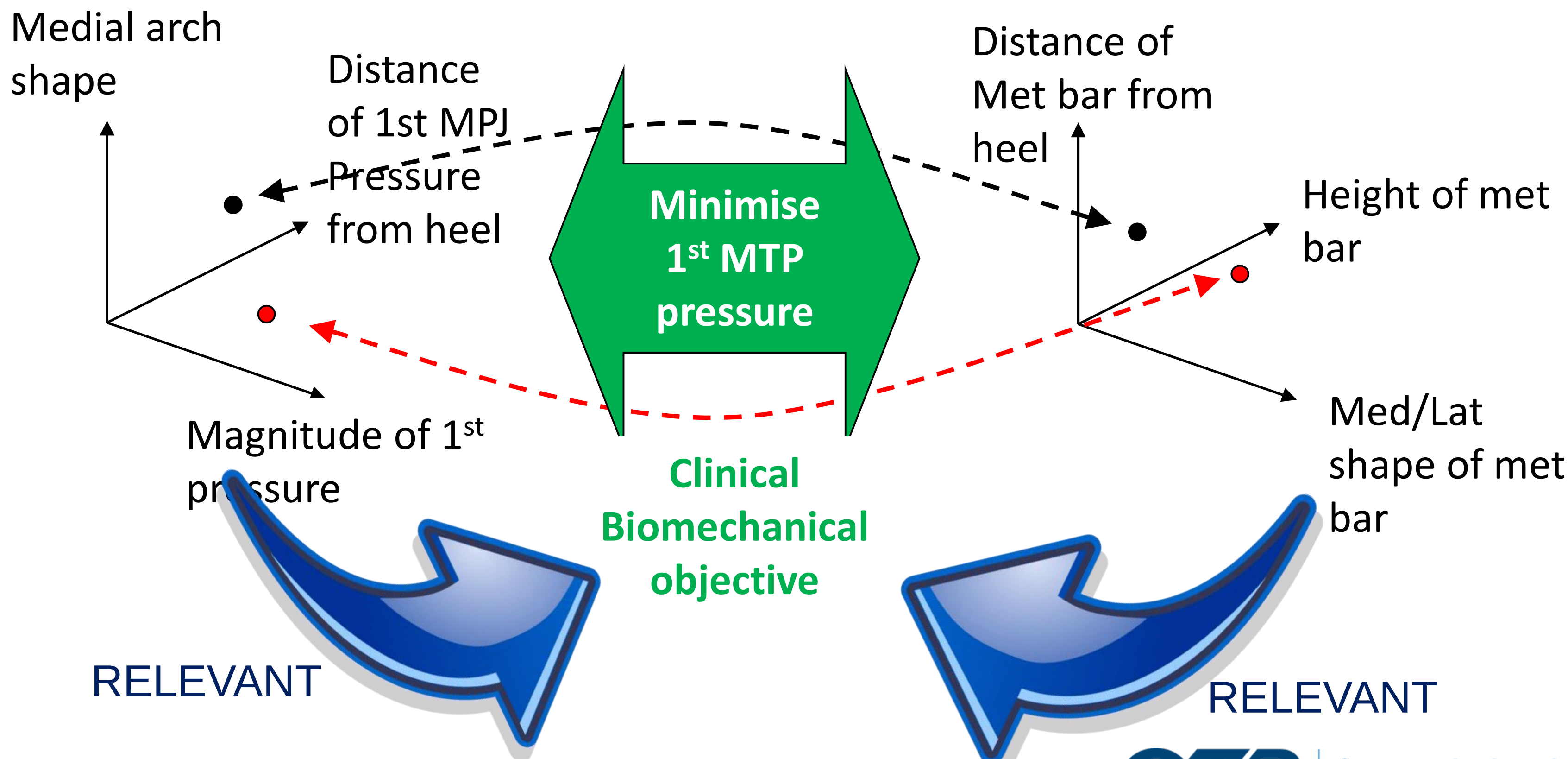


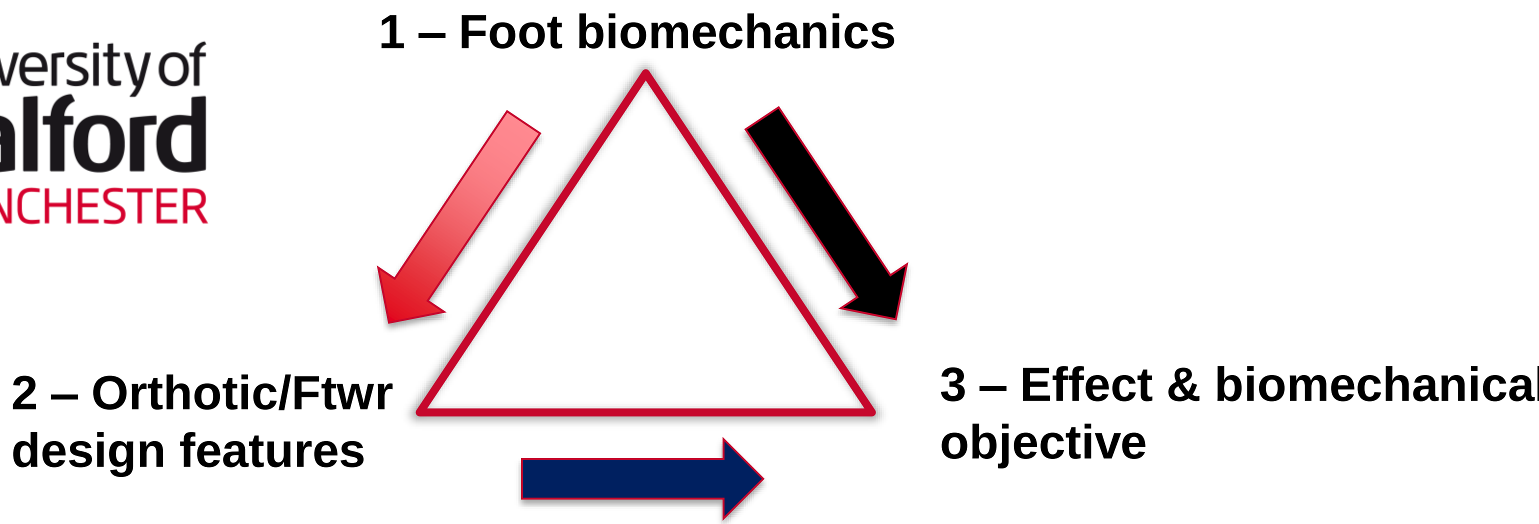

OTB Ortopedtekniska Branschrådet

We need to build ***explicit relationships*** between

(1) foot biomechanics

(2) orthotic / footwear designs

(3) orthotic / footwear effects




**Lets answer……**

1. Do we know how changing orthotic/footwear features affects plantar pressure? (2 to 3)

2. Are we measuring the right foot characteristics to be able to predict the BEST off loading designs? (1 to 2)

3. Is the hassle/cost of getting (MEASURING?) foot data worth it in terms of the orthotic/footwear achieving its aim? (1 to 3)

1. Use of **foot biomechanics data** to optimise rocker footwear for pressure reduction in diabetes


Clinical Biomechanics 28 (2013) 679–685

Contents lists available at SciVerse ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes

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ARTICLE INFO

Article history:
Received 6 March 2013
Accepted 13 May 2013

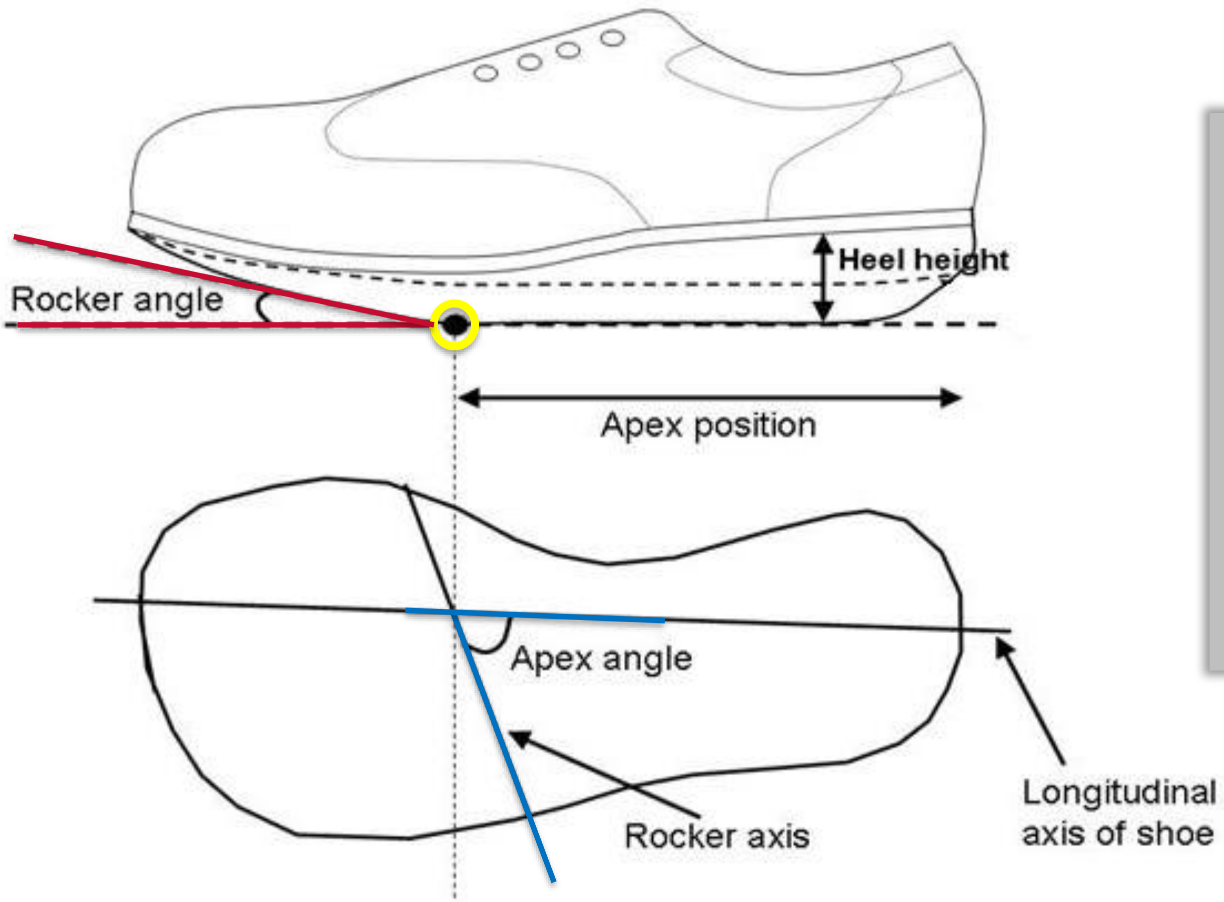
Keywords:
Rocker shoe
Footwear
Plantar pressure
Diabetes

ABSTRACT

Background: There is no consensus on the precise rocker shoe outsole design that will optimally reduce plantar pressure in people with diabetes. This study aimed to understand how peak plantar pressure is influenced by systematically varying three design features which characterise a curved rocker shoe: apex angle, apex position and rocker angle.
Methods: A total of 12 different rocker shoe designs, spanning a range of each of the three design features, were tested in 24 people with diabetes and 24 healthy participants. Each subject also wore a flexible control shoe. Peak plantar pressure, in four anatomical regions, was recorded for each of the 13 shoes during walking at a controlled speed.
Findings: There were a number of significant main effects for each of the three design features, however, the precise effect of each feature varied between the different regions. The results demonstrated maximum

2. Use of **plantar pressure data** to optimise orthotic features under the forefoot

# Rocker = 3 DESIGN features




1. Apex Position

2. Rocker Angle

3. Apex Angle

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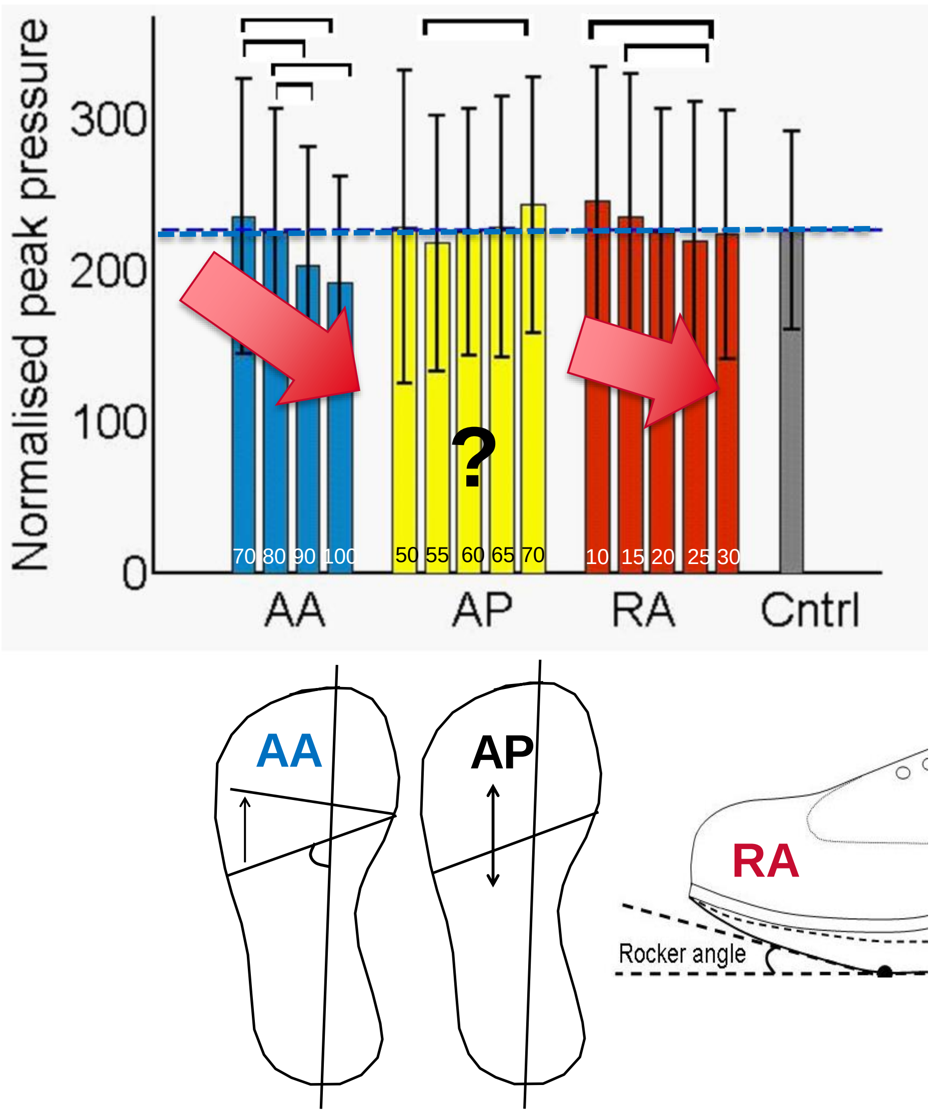
# Study 1: Rocker angle vs Apex position vs Apex Angle

- ✓ n=30 diabetes
- ✓ Controlled walking speed
- ✓ Plantar pressure in 12 shoes (variations of RA, AP, AA)

| Shoe | Rocker angle (RA) | Apex position (AP) | Apex angle (AA) |
|---|---|---|---|
| 1 (control) | (Heel height) | - | - |
| 2 (reference*) | 20º (3 cm) | 60% | +80º |
| 3 (RA1) | 10º (1 cm ) | 60% | +80º |
| 4 (RA2) | 15º (2 cm ) | 60% | +80º |
| 5 (RA4) | 25º (4 cm ) | 60% | +80º |
| 6 (RA5) | 30º (5 cm ) | 60% | +80º |
| 7(AP1) | 20º (3 cm ) | 50% | +80º |
| 8 (AP2) | 20º (3 cm ) | 55% | +80º |
| 9 (AP4) | 20º (3 cm ) | 65% | +80º |
| 10 (AP5) | 20º (3 cm ) | 70% | +80º |
| 11 (AA1) | 20º (3 cm ) | 60% | 70º |
| 12 (AA2) | 20º (3 cm ) | 60% | 90º |
| 13 (AA4) | 20º (3 cm ) | 60% | 100º |

# Mean effect: 1st MPJ




Pressure decreased Apex angle increased (more perpendicular):

No consistent change in pressure

Slight decrease in pressure as rocker angle increased

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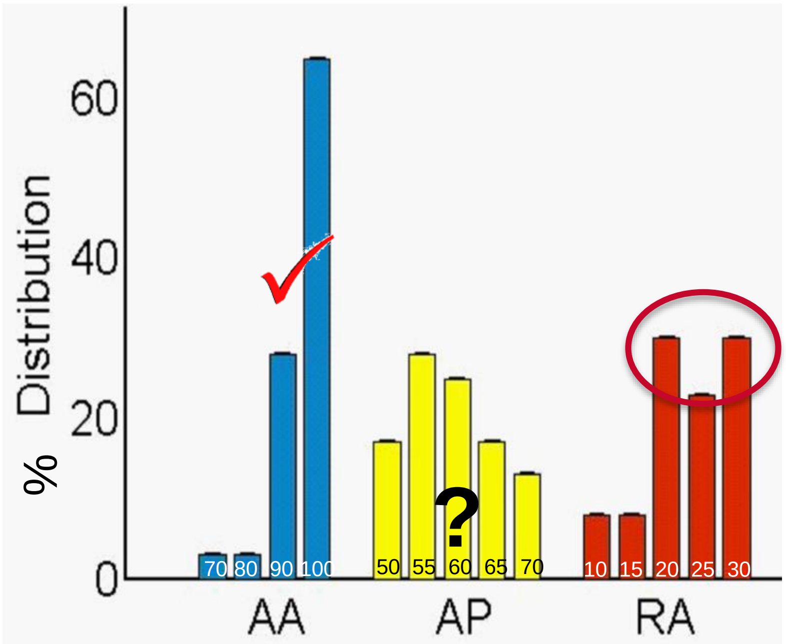
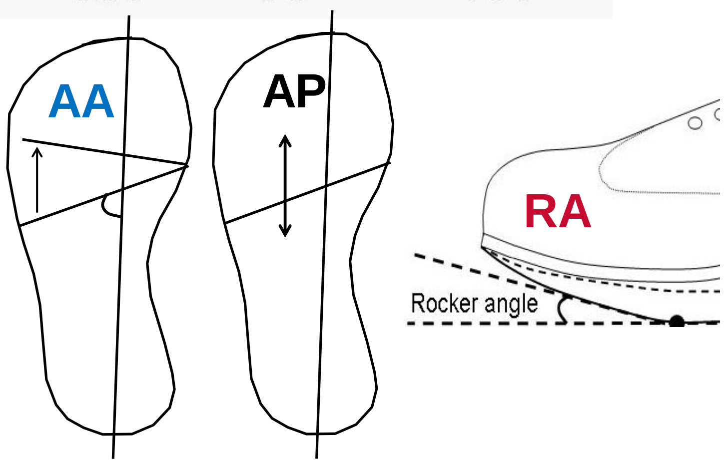
# Distribution of optimal design



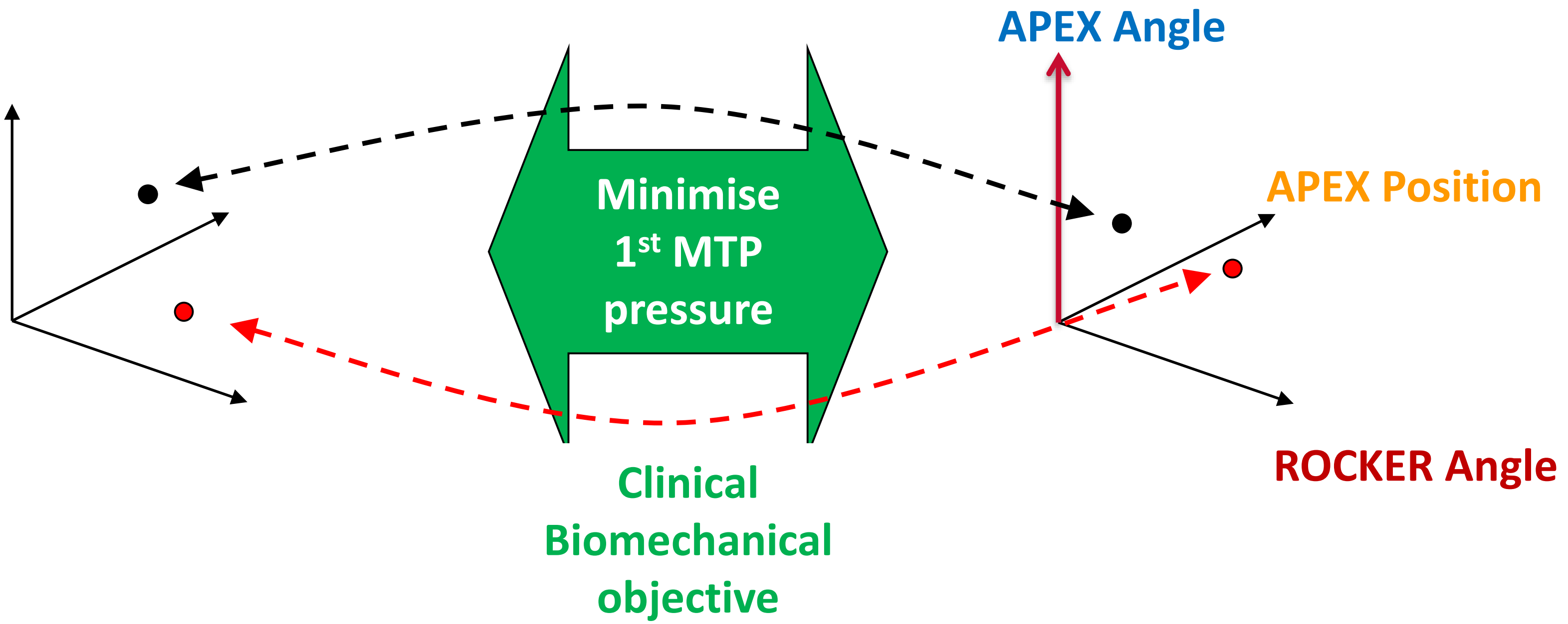

- **Apex Angle** – 90˚ and 100 ˚ are BEST for **>90% of participants**
- NO BEST **Apex POSITION –** optimal position different greatly.
- NO BEST **Rocker Angle**, but 3/5 higher angles gave better results

Ortopedtekniska Branschrådet

# Outcomes study 1

- Apex ANGLE is optimised = 95˚ ✓
- Investigate **APEX POSITION** further – person specific response
- Need to establish interaction between **Rocker ANGLE** and **Apex POSITION**

# Study 2: Understanding the effect of varying rocker angle and apex position on plantar pressure.



# Varying Rocker angle and Apex position

- **n= 87** with diabetes (Salford & Cologne)

| Shoe | Rocker angle (RA) | Apex position (AP) |
|---|---|---|
| 1 | 15º | 52% |
| 2 | 15º | 57% |
| 3 | 15º | 62% |
| 4 | 15º | 67% |
| 5 | 20º | 52% |
| 6 | 20º | 57% |
| 7 | 20º | 62% |
| 8 | 20º | 67% |

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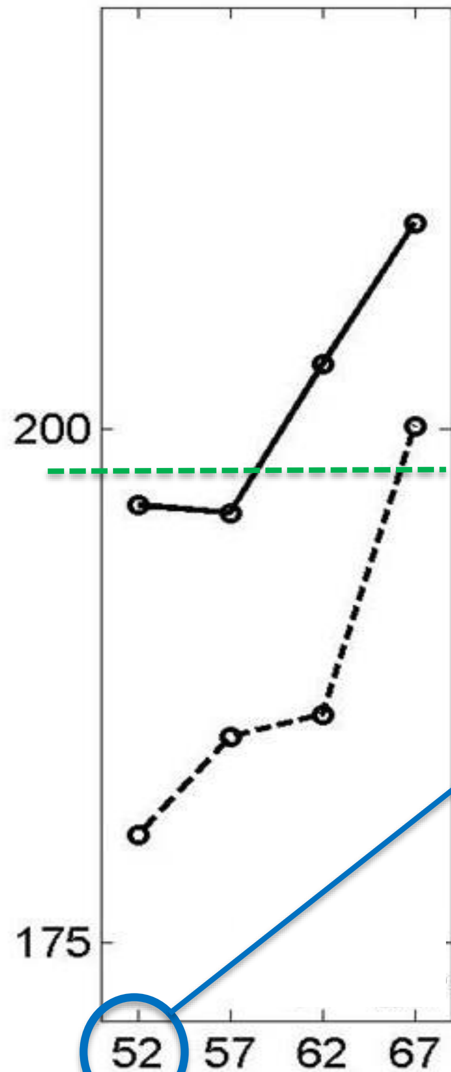
# 1st MPJ




15˚ Rocker Angle

20˚ Rocker Angle

Pressure kPa

Apex position
% of shoe length

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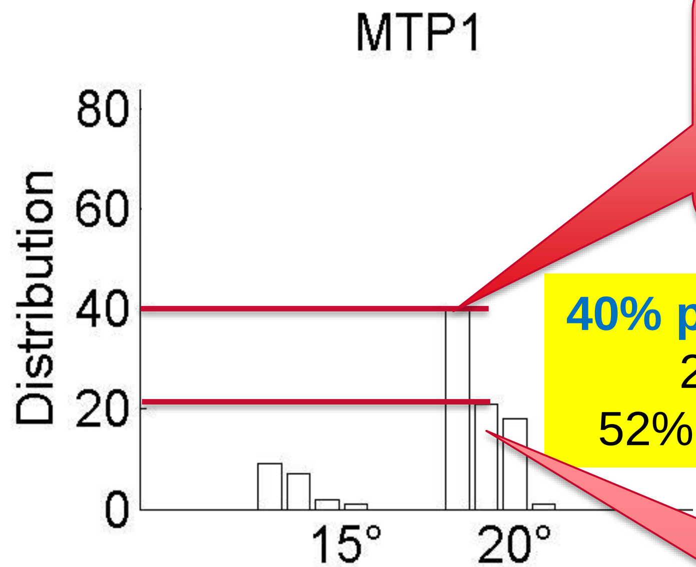



**What about the other 60% of people?**

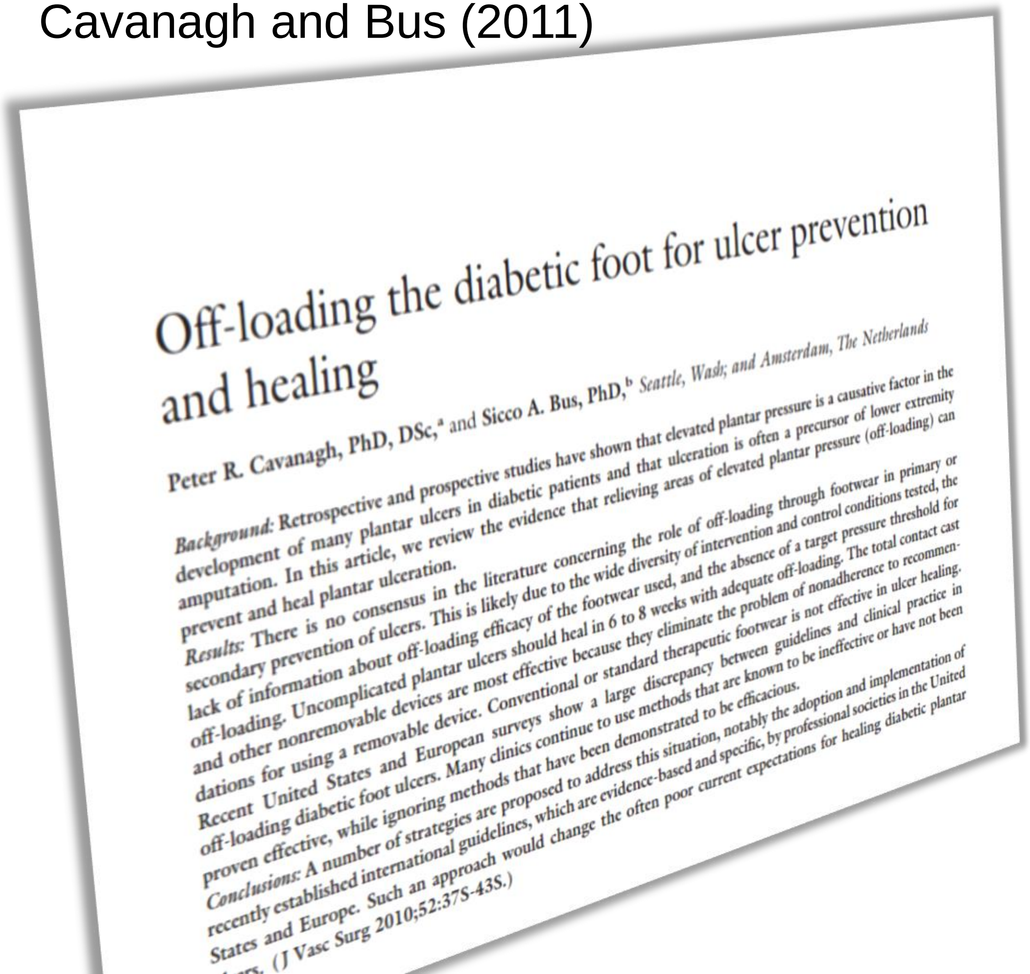
**40% patients best =**
20˚ rocker
52% of shoe length

**What about in between 52% and 57%?**

What is the compromise if we give everyone the **GROUP BEST** versus their own **PERSONAL BEST**?

# PERSONAL best vs GROUP best shoe

Owings et al (2009).
Cavanagh and Bus (2011)



Off-loading the diabetic foot for ulcer prevention and healing

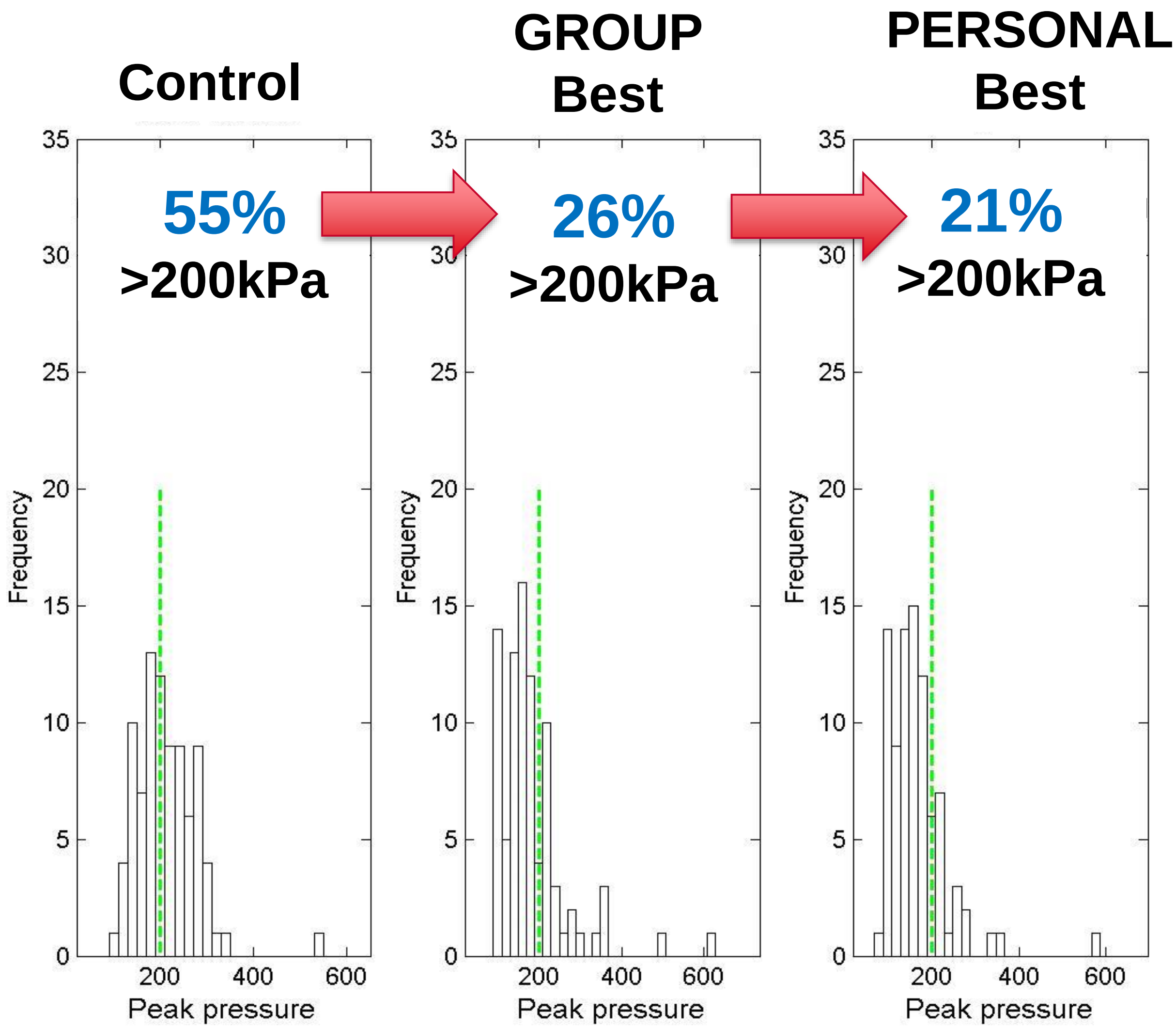
Peter R. Cavanagh, PhD, DSc,[a] and Sicco A. Bus, PhD,[b] Seattle, Wash; and Amsterdam, The Netherlands

*Background:* Retrospective and prospective studies have shown that elevated plantar pressure is a causative factor in the development of many plantar ulcers in diabetic patients and that ulceration is often a precursor of lower extremity amputation. In this article, we review the evidence that relieving areas of elevated plantar pressure (off-loading) can prevent and heal plantar ulceration.
*Results:* There is no consensus in the literature concerning the role of off-loading through footwear in primary or secondary prevention of ulcers. This is likely due to the wide diversity of the footwear used, of intervention and control conditions tested, the lack of information about off-loading efficacy of the footwear used, and the absence of a target pressure threshold for off-loading. Uncomplicated plantar ulcers should heal in 6 to 8 weeks with adequate off-loading. The total contact cast and other nonremovable devices are most effective because they eliminate the problem of nonadherence to recommendations for using a removable device. Conventional or standard therapeutic footwear is not effective in ulcer healing. Recent United States and European surveys show a large discrepancy between guidelines and clinical practice in off-loading diabetic foot ulcers. Many clinics continue to use methods that are known to be ineffective or have not been proven effective, while ignoring methods that have been demonstrated to be efficacious.
*Conclusions:* A number of strategies are proposed to address this situation, notably the adoption and implementation of recently established international guidelines, which are evidence-based and specific, by professional societies in the United States and Europe. Such an approach would change the often poor current expectations for healing diabetic plantar ulcers. (J Vasc Surg 2010;52:37S-43S.)

*“ It may be that such a threshold is unique to each individual, but the* ***200 kPa value can serve as a goal for plantar off-loading*** *until better evidence is available.”*

**How many people**
**< 200kPa?**

# PERSONAL best vs GROUP best shoe
## How many people < 200kPa?



# PERSONAL best vs GROUP best shoe
## How many people < 200kPa?

**You would need to give bespoke footwear to 100 people to get 5 extra people below 200 kPa**

**Is it worth it?**

**Can we short cut the decision as to who needs bespoke footwear ?**

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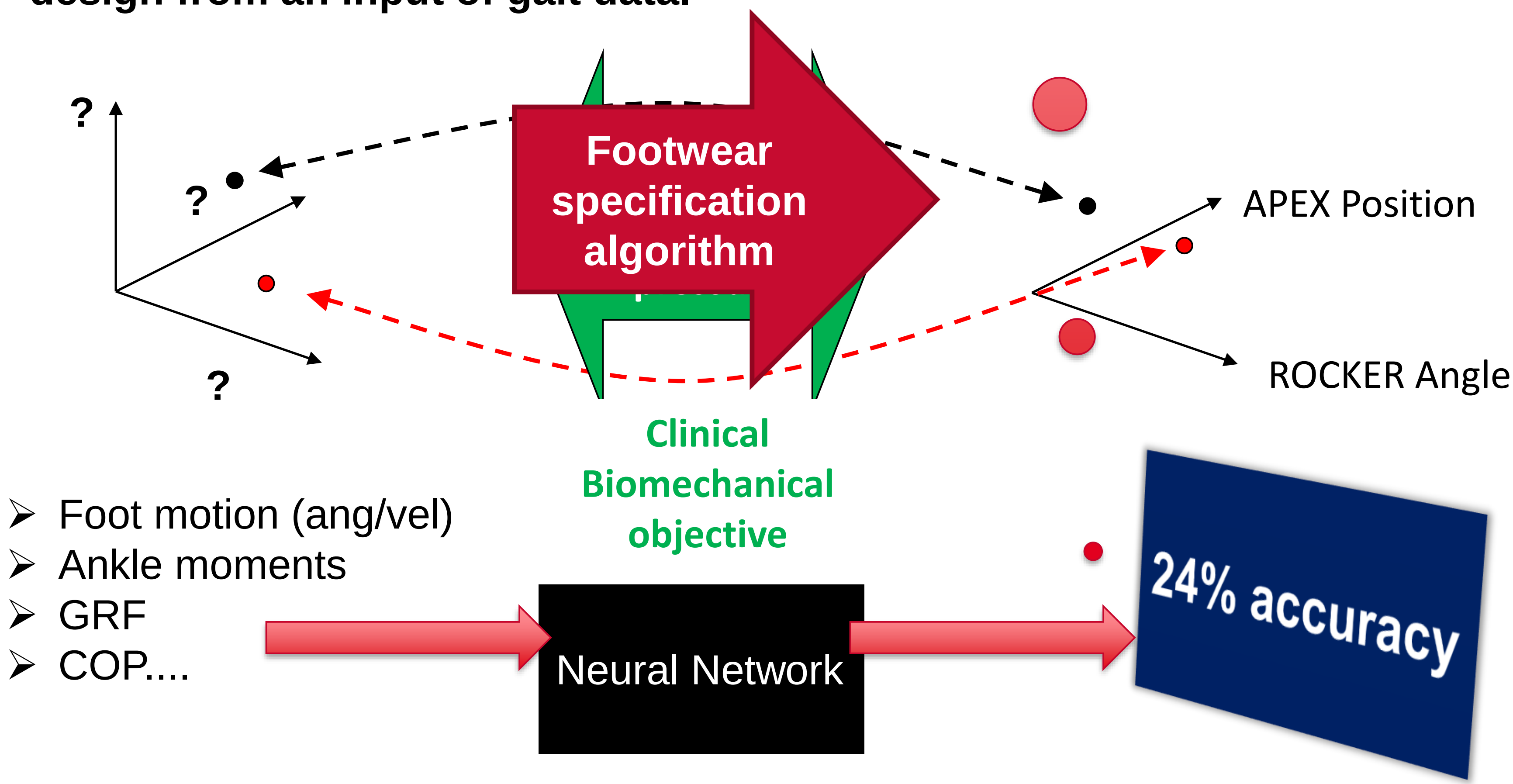
“Trial and error?”

**Study 3: Developing an algorithm to predict optimal rocker shoe design from an input of gait data.**



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**YES –**
**Apex Angle**
**Apex Position**
**Rocker Angle**

**NO –**
**Wrong measures?**
**Too complex?**
**Multiple Optimal designs**

**Lets answer……**

1. Do we know how changing footwear featu ... ects plantar pressure variables we want to control? ... o 3)

2. Are we measuring the right foot characteristics to be able to predict the BEST off loading footwear designs? (1 to 2)

3. Is the hassle/cost of getting (MEASURING ?) foot data worth it in terms of the footwear achieving i

**NO –**
**Apex Angle = 95°**
**Apex Position = 55%**
**Rocker Angle = 20°**

**Patient specific customisation of rocker soles is trial and error**
**– go for good design**
***(+ there is an evidence base for it)***

**AXIS 1:**

**Position of Met Bar – (a) next to peak pressure, (b) proximal to it, or c) distal to it?**

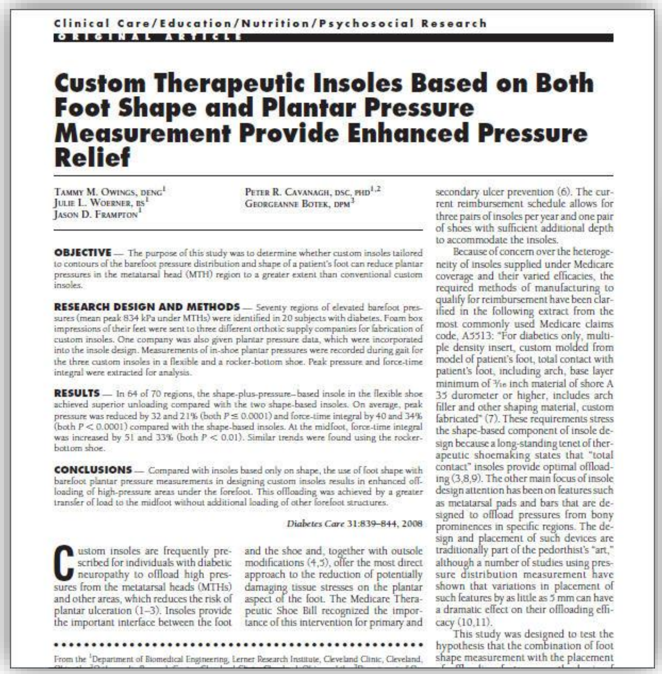
**Distance of Met bar from Pressure**

**AXIS 2:**

a) Poron
b) EVA
c) "no material" or *void*.

**Material**

**Shape of met bar**


Clinical Care/Education/Nutrition/Psychosocial Research

ORIGINAL ARTICLE

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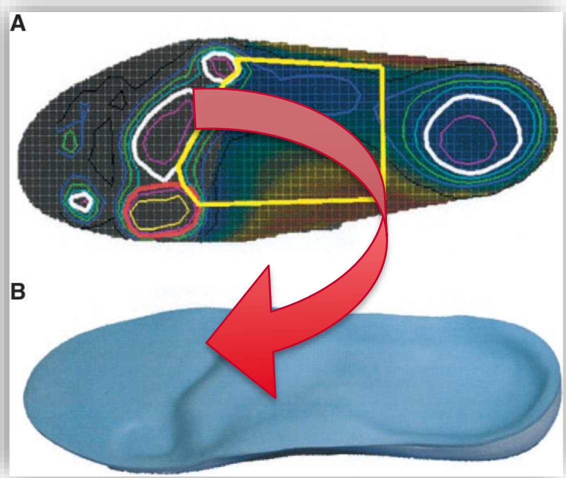
Because of concern over the heterogeneity of insoles supplied under Medicare coverage and their varied efficacies, the required methods of manufacturing to qualify for reimbursement have been clarified in the following extract from the most commonly used Medicare claims code, A5513: "For diabetics only, 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 inch material of shore A 35 durometer or higher, includes arch filler and other shaping material, custom fabricated" (7). These requirements stress the shape-based component of insole design because a long-standing tenet of therapeutic shoemaking states that "total contact" insoles provide optimal offloading (3,8,9). The other main focus of insole design attention has been on features such as metatarsal pads and bars that are designed to offload pressures from bony prominences in specific regions. The design and placement of such devices are traditionally part of the pedorthist's "art," although a number of studies using pressure distribution measurement have shown that variations in placement of such features by as little as 5 mm can have a dramatic effect on their offloading efficacy (10,11).

This study was designed to test the hypothesis that the combination of foot shape measurement with the placement

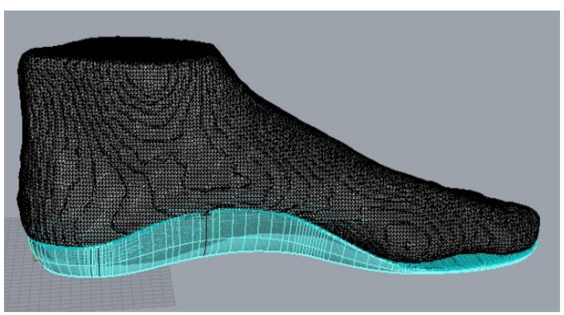
From the [1]Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic, Cleveland,

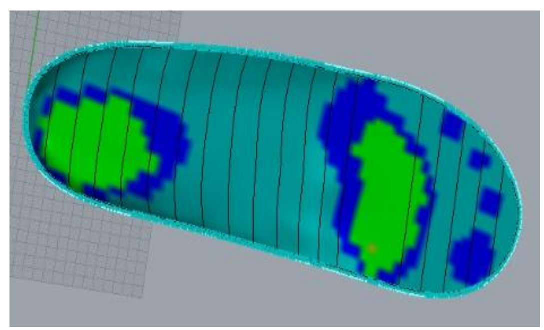


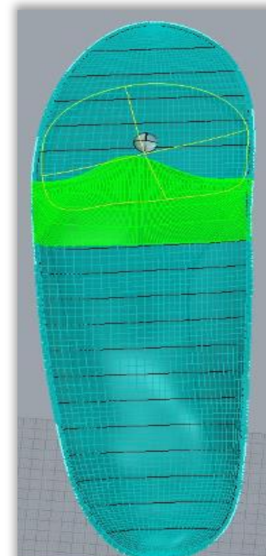

**Bespoke - Determined by peak pressure**

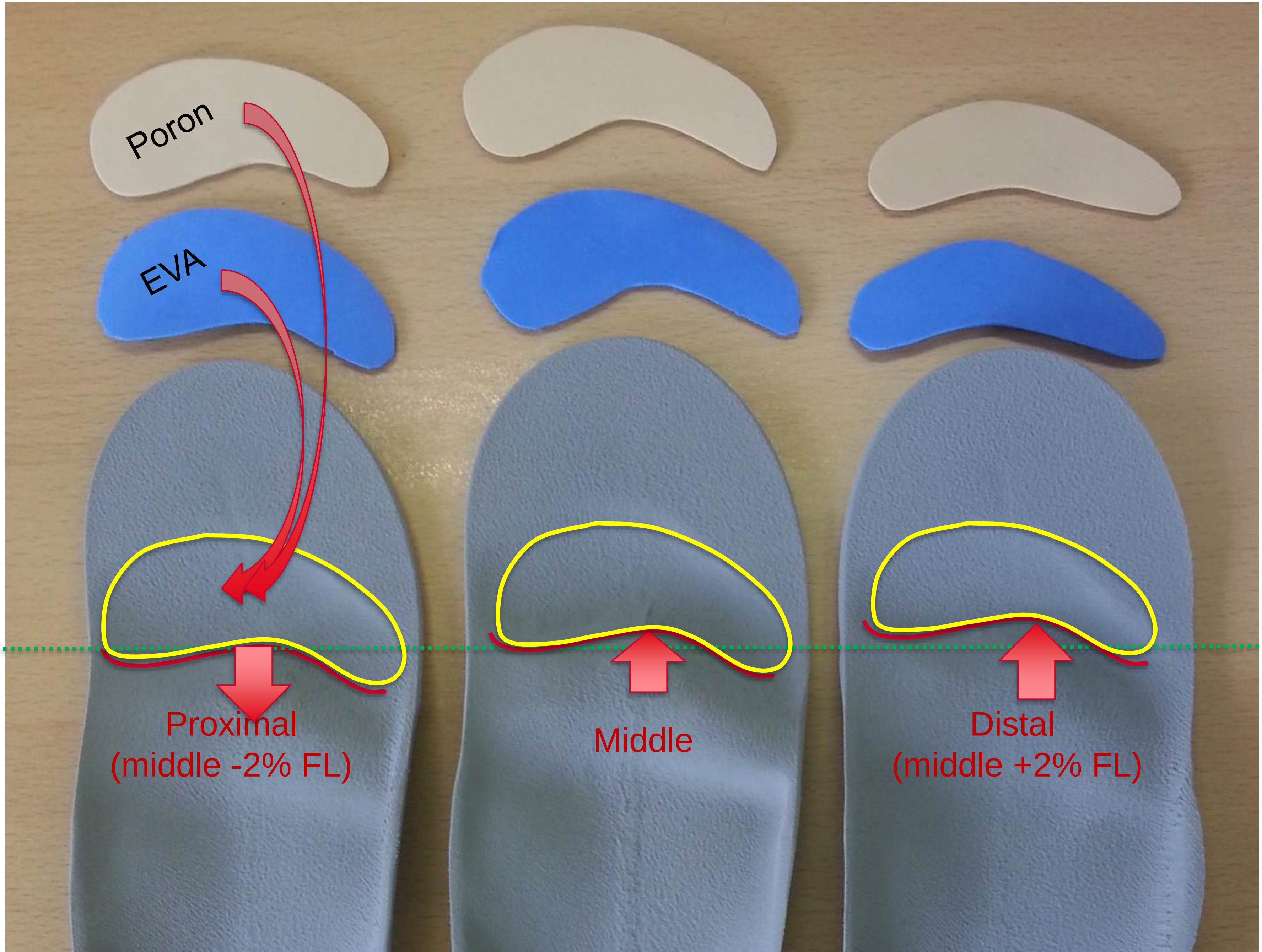
# Input data to the orthotic design:

1. 3D foot scan
2. Plantar pressure data



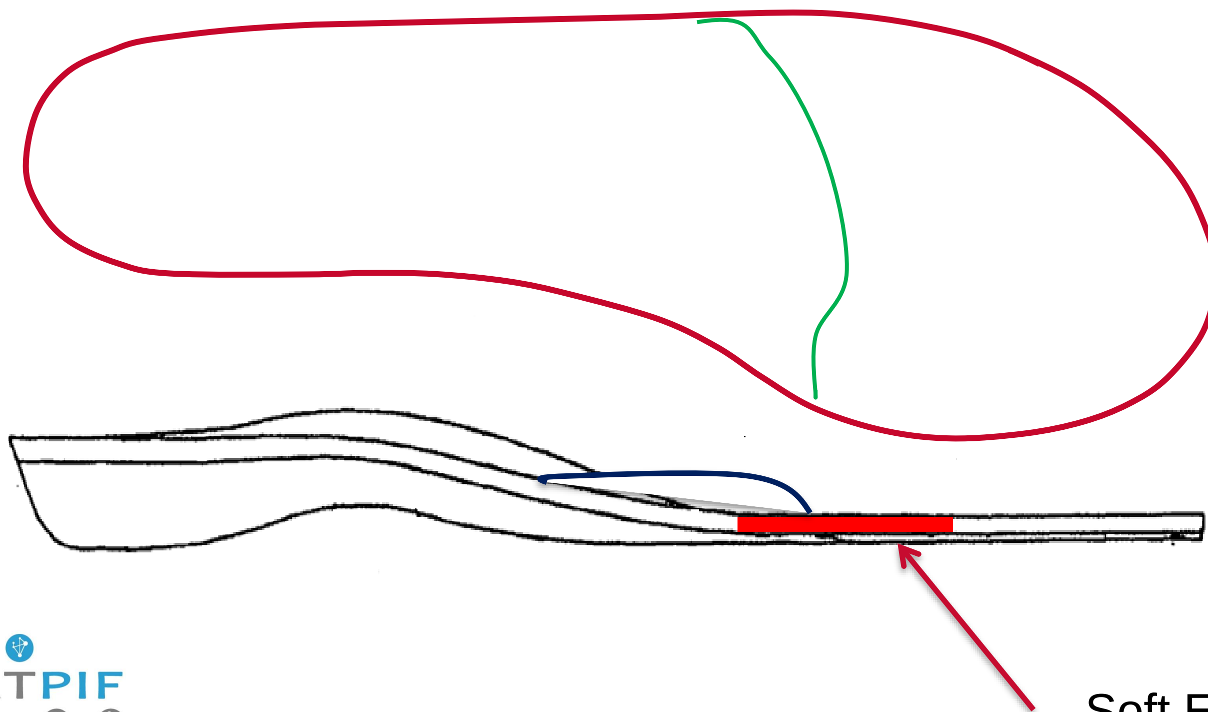





Poron
EVA
Proximal
(middle -2% FL)
Middle
Distal
(middle +2% FL)

# Insole 1

| | | AXIS 1 | | |
|---|---|---|---|---|
| | | Distal | Middle | Proximal |
| AXIS 2 | EVA | Insole 1 | Insole 2 | Insole 3 |
| | Poron | Insole 4 | Insole 5 | Insole 6 |
| | Void | Insole 7 | Insole 8 | Insole 9 |



Soft EVA

# Data collection

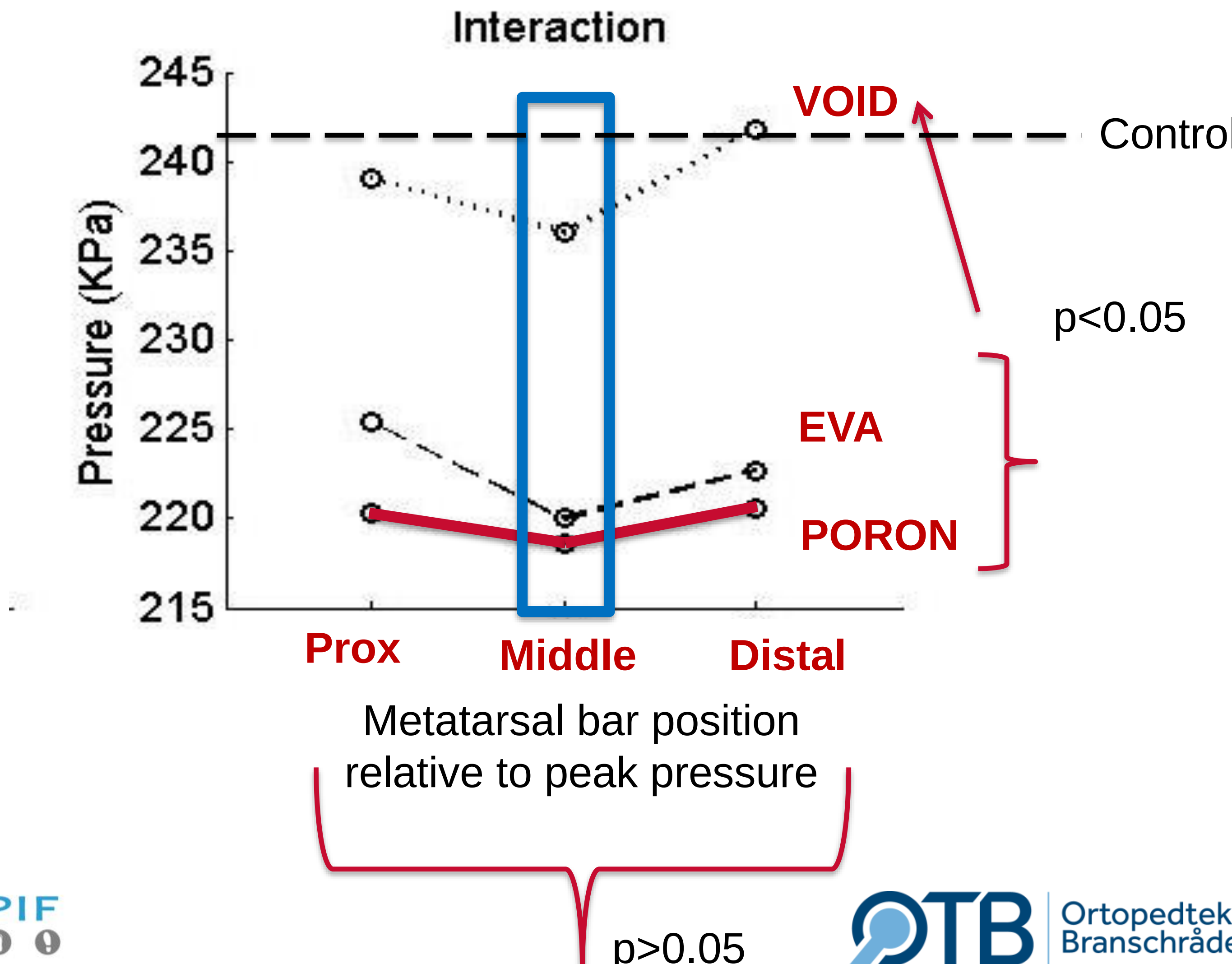
**Sample:**

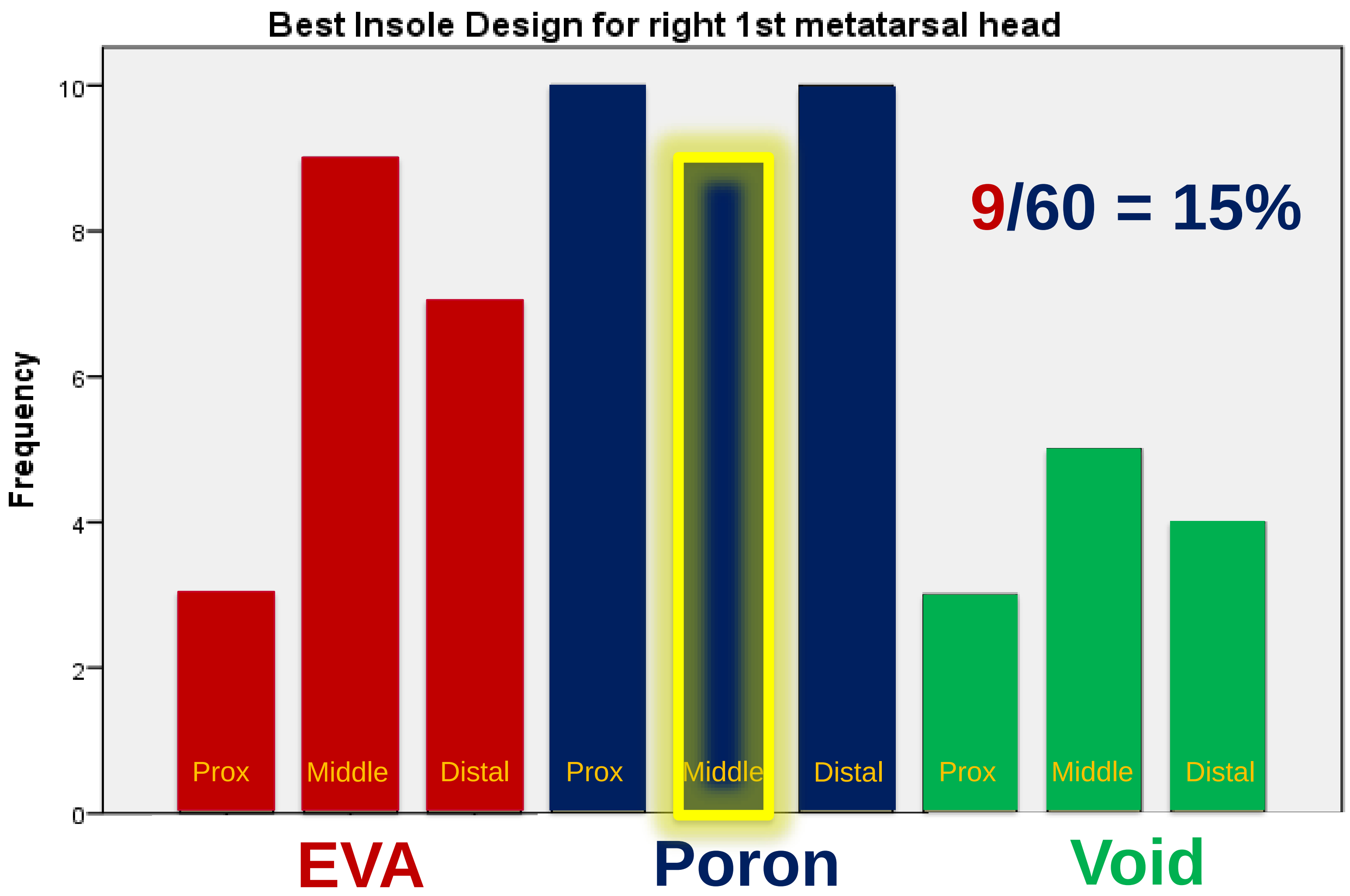
- n=60 diabetic patients with neuropathy with no history of previous ulceration

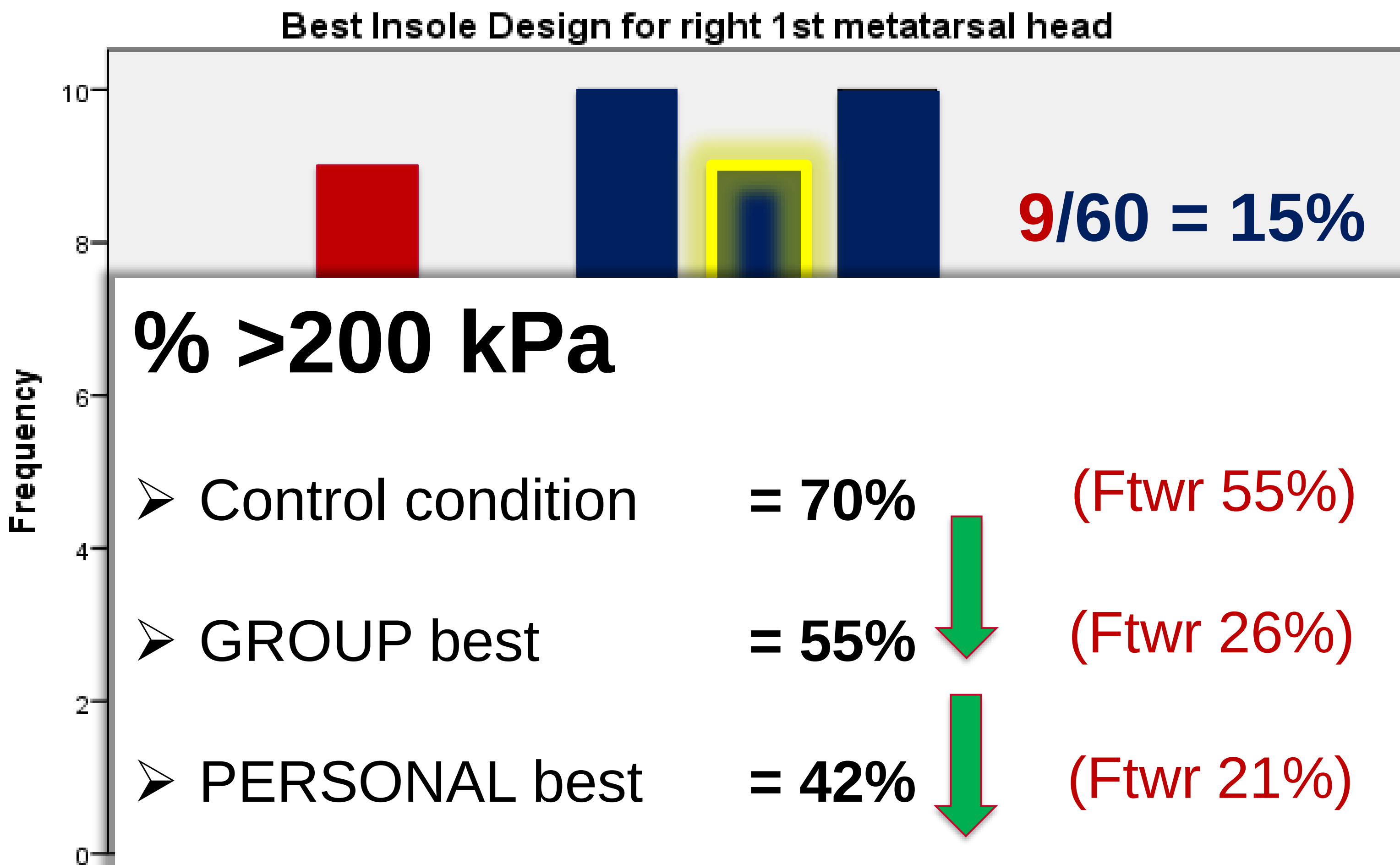
**Shoes:**

- Retail shoes: achieve the highest offloading without changing patient's shoe

# What is best ?


Interaction
Pressure (KPa)
245
240
235
230
225
220
215
VOID
Control
p<0.05
EVA
PORON
Prox
Middle
Distal
Metatarsal bar position
relative to peak pressure
p>0.05


Best Insole Design for right 1st metatarsal head
Frequency
0
2
4
6
8
10
9/60 = 15%
Prox
Middle
Distal
Prox
Middle
Distal
Prox
Middle
Distal
EVA
Poron
Void




# % >200 kPa

- ➢ Control condition = **70%** (Ftwr 55%)
- ➢ GROUP best = **55%** (Ftwr 26%)
- ➢ PERSONAL best = **42%** (Ftwr 21%)

Personalising helps **13 extra people**

**YES –**
**Met bar position, material**

**NO –**

**Lets answer……**

1. Do we know how changing orthotic featu ects plantar pressure variables we want to control? o 3)

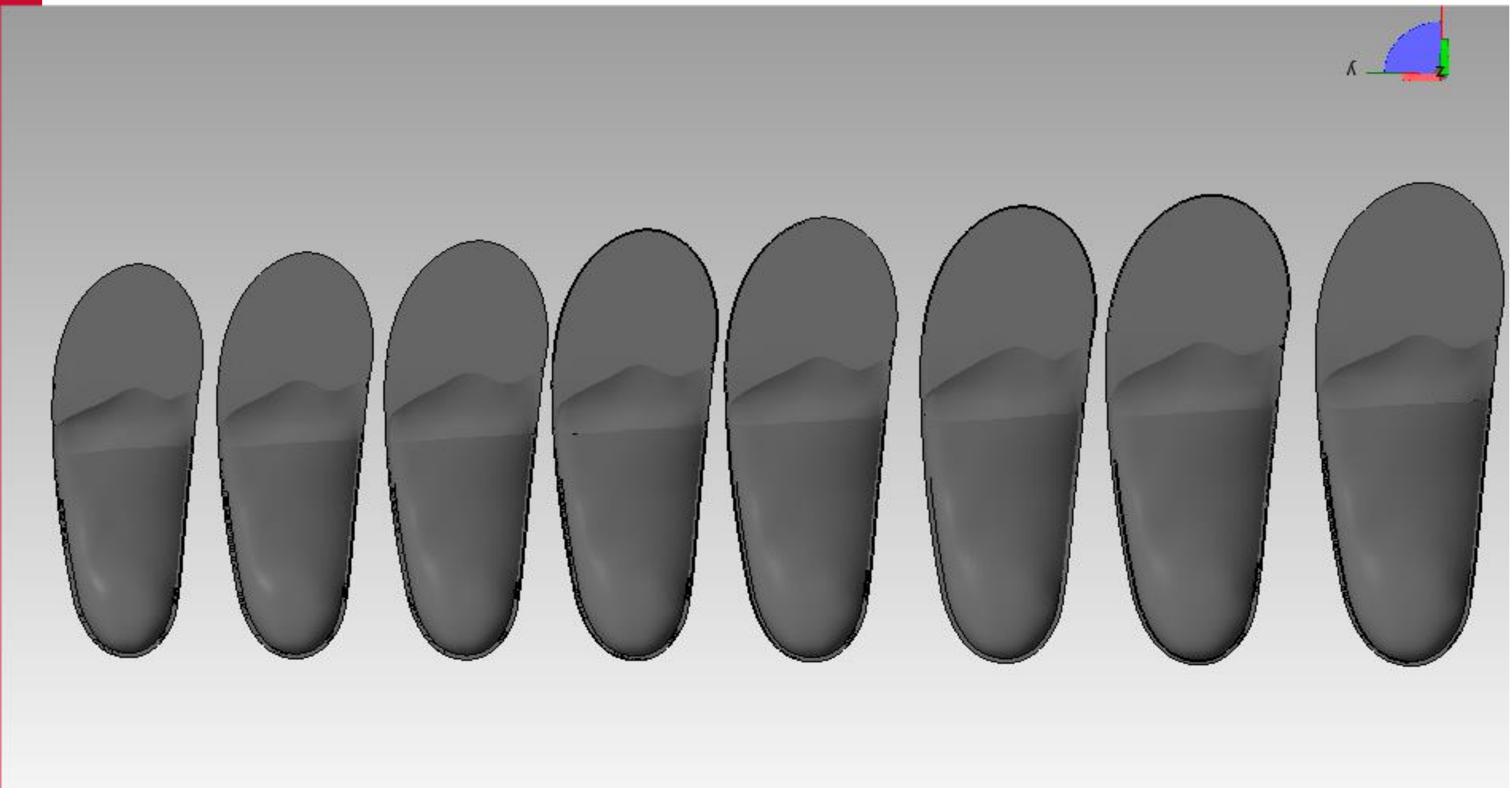
2. Are we measuring the right foot characteristics to be able to predict the BEST off loading orthotic designs? (1 to 2)

3. Is the hassle/cost of getting (MEASURING ?) foot data worth it in terms of the orthotic achieving it

**NO/YES**
**Met bar in the middle**
**Poron or EVA**

University of Salford MANCHESTER

# Optimised design now available as prefabricated orthosis



# Foot biomechanics in diabetes and off loading strategies

1) If you want to reduce pressure - Footwear 1st line, Orthoses 2nd line

2) Data has given us evidenced designs

**Apex Angle = 95˚**

**Apex Position = 55%**

**Rocker Angle = 20˚**

**Met bar at the site of pressure, Poron or EVA**

3) We can do better

**26% still >200kPa in Rocker Shoes**

**55% >200 kPa in orthoses**

but we need to use personalised data to get the optimised designs, on each patient.....and its not worth it/difficult to predict

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https://twitter.com/ProfChrisNester