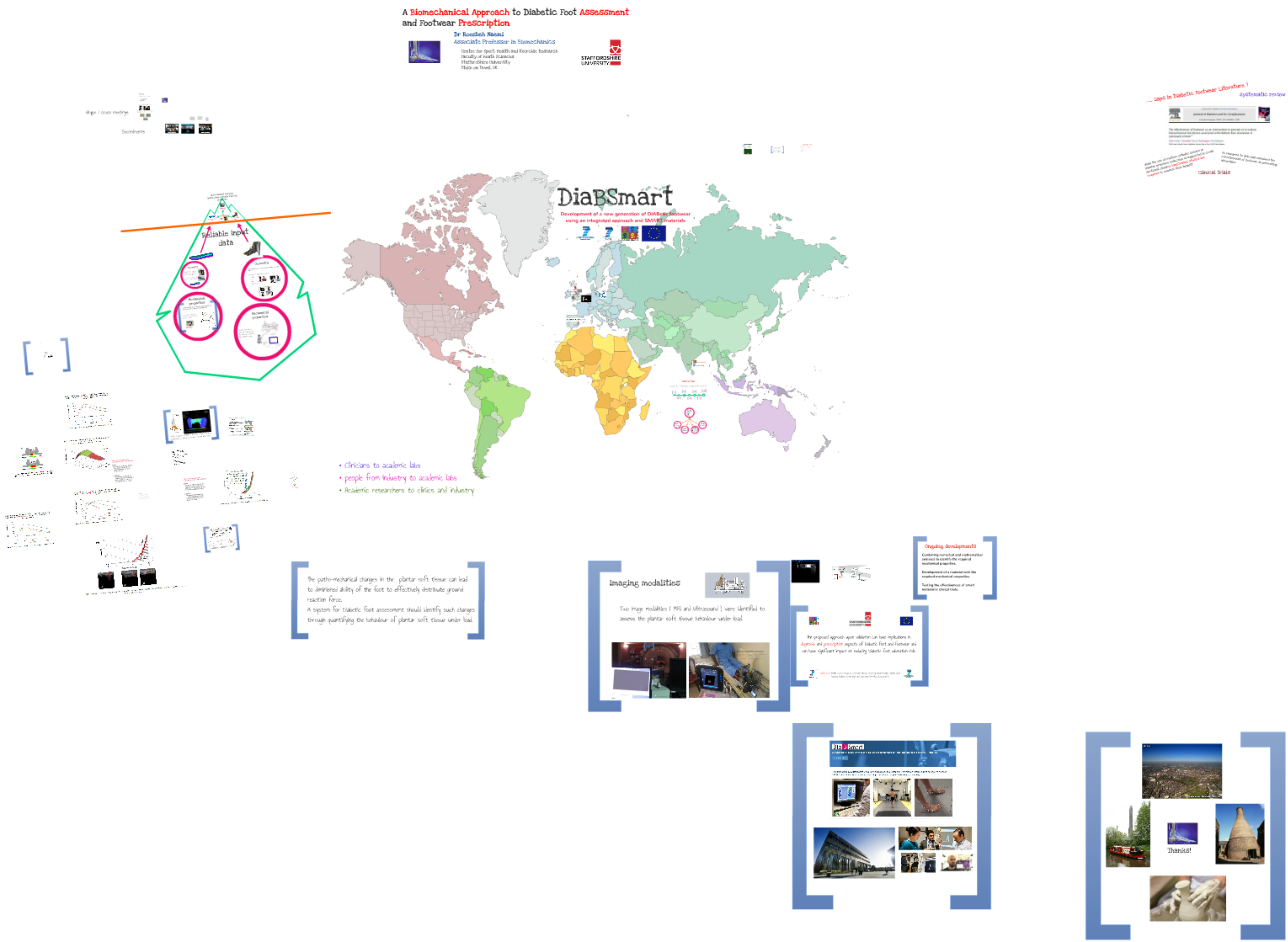
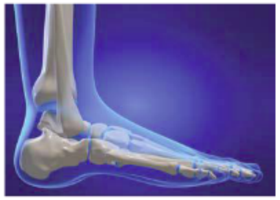

A Biomechanical Approach to Diabetic Foot Assessment and Footwear Prescription
Dr Roozbeh Naemi
Associate Professor in Biomechanics
Staffordshire University
STAFFORDSHIRE UNIVERSITY
DiaBSmart
Development of a new generation of DIABetic footwear using an integrated approach and SMART materials
Reliable input data
• Clinicians to academic labs
• people from industry to academic labs
• Academic researchers to clinics and industry
The patho-mechanical changes in the plantar soft tissue can lead to diminished ability of the foot to effectively distribute ground reaction force.
A system for diabetic foot assessment should identify such changes through quantifying the behaviour of plantar soft tissue under load.
imaging modalities
Two image modalities (MRI and Ultrasound) were identified to assess the plantar soft tissue behaviour under load.
Ongoing developments
The proposed approach upon validation can have implications in diagnosis and prescription aspects of diabetic foot and footwear and can have significant impact on reducing diabetic foot ulceration risk.
Clinical Trials
Systematic review
Thanks!

A Biomechanical Approach to Diabetic Foot Assessment and Footwear Prescription



Dr Roozbeh Naemi

Associate Professor in Biomechanics

Centre for Sport, Health and Exercise Research
Faculty of Heath Sciences
Staffordshire University
Stoke on Trent, UK

STAFFORDSHIRE UNIVERSITY

DiaBSmart

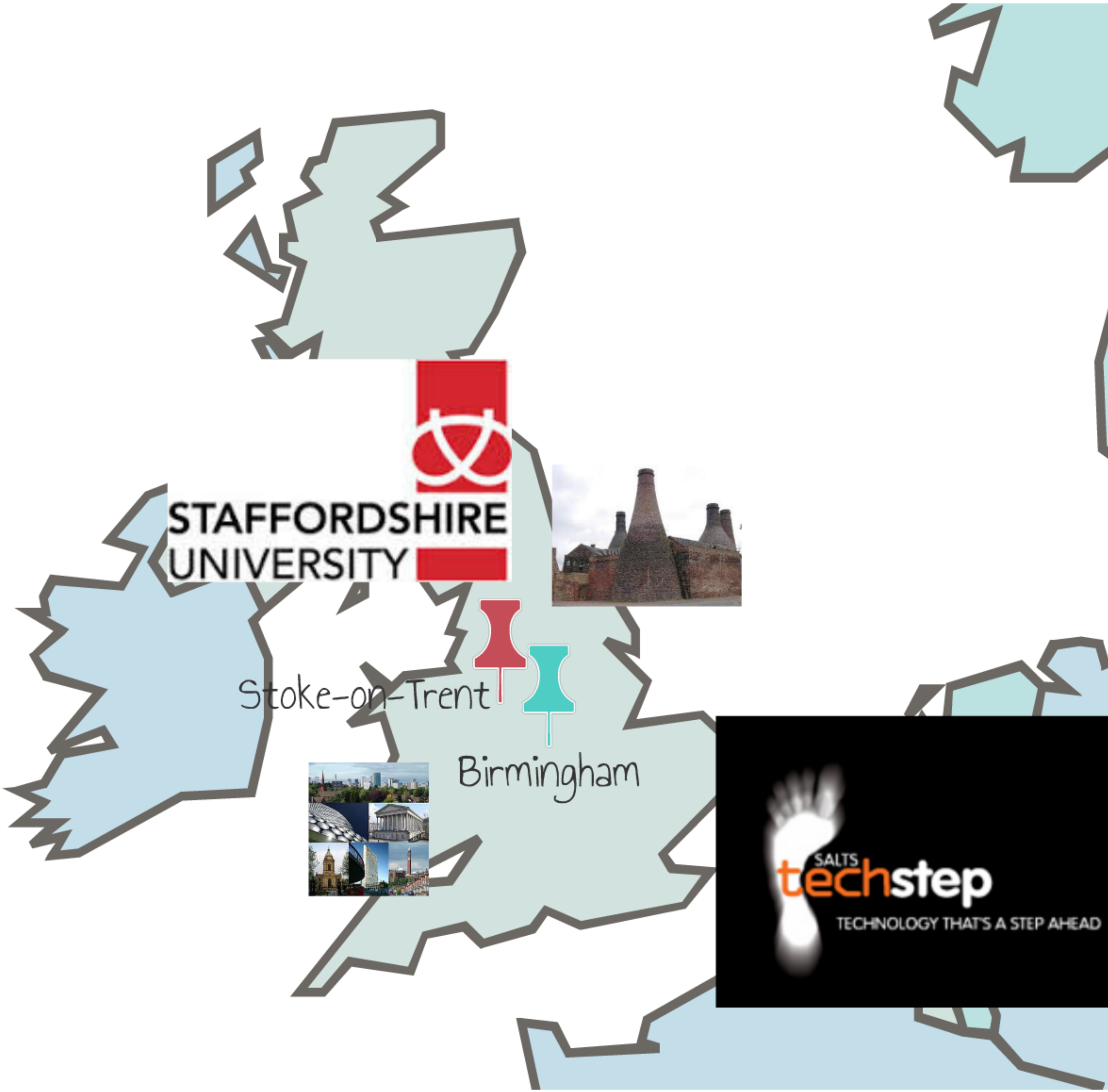
Development of a new generation of DIABetic footwear using an integrated approach and SMART materials

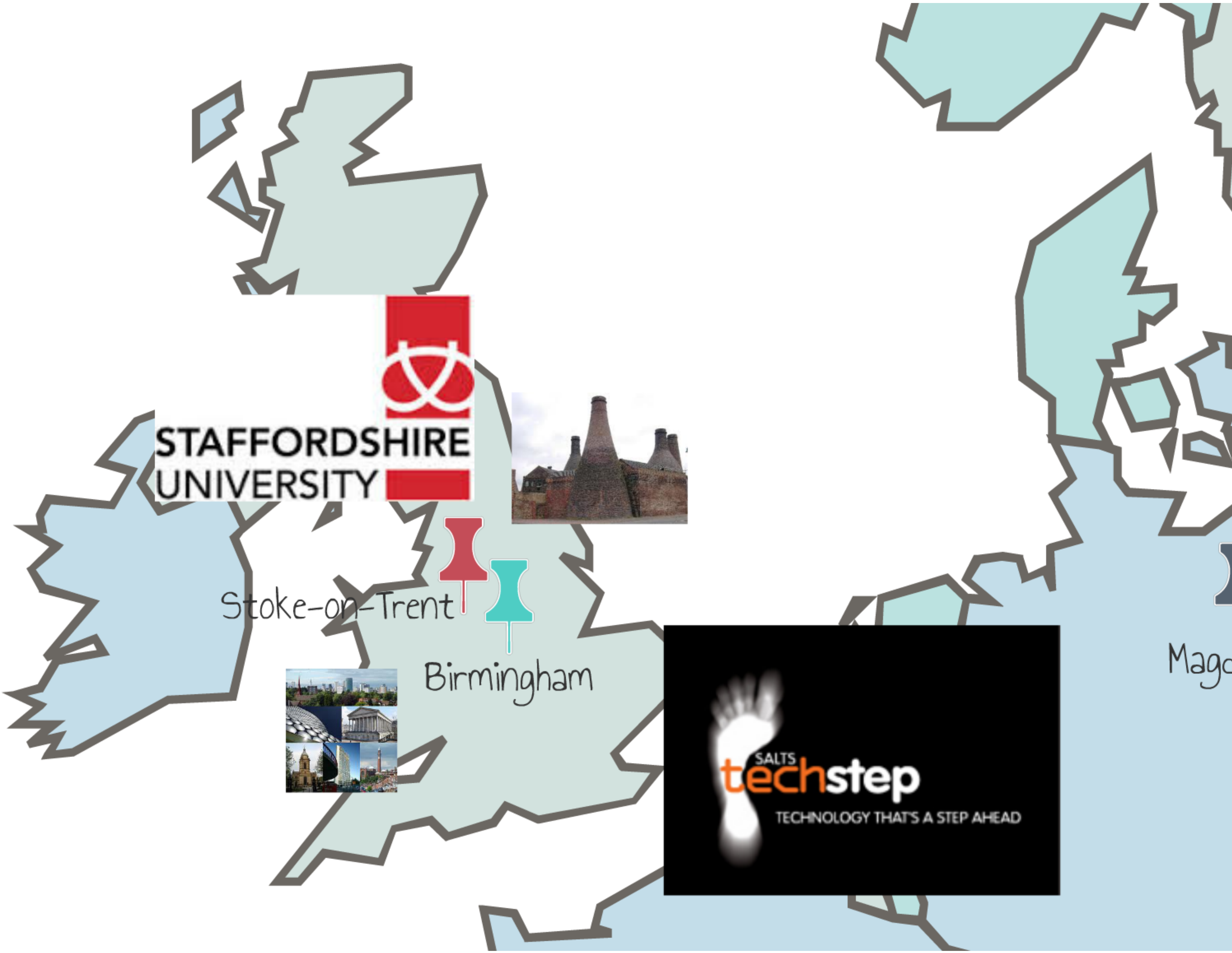
Aims and Objectives

DiabSmart project has an overarching aim of Knowledge generation and transfer between academic, clinical and manufacturing sectors to enable the development of a new generation of diabetic footwear.

The main objectives are:

(1) to develop an integrated system of diabetic foot assessment and footwear prescription,
(2) to validate the developed system using experimental methods,
(3) to develop a suitable insole material to meet the mechanical and clinical requirements,
(4) to evaluate the mechanical and clinical effectiveness of insole material choice in reducing the risk of foot ulcerations.


STAFFORDSHIRE UNIVERSITY
Stoke-on-Trent
Birmingham
SALTS techstep
TECHNOLOGY THAT'S A STEP AHEAD


STAFFORDSHIRE
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techstep
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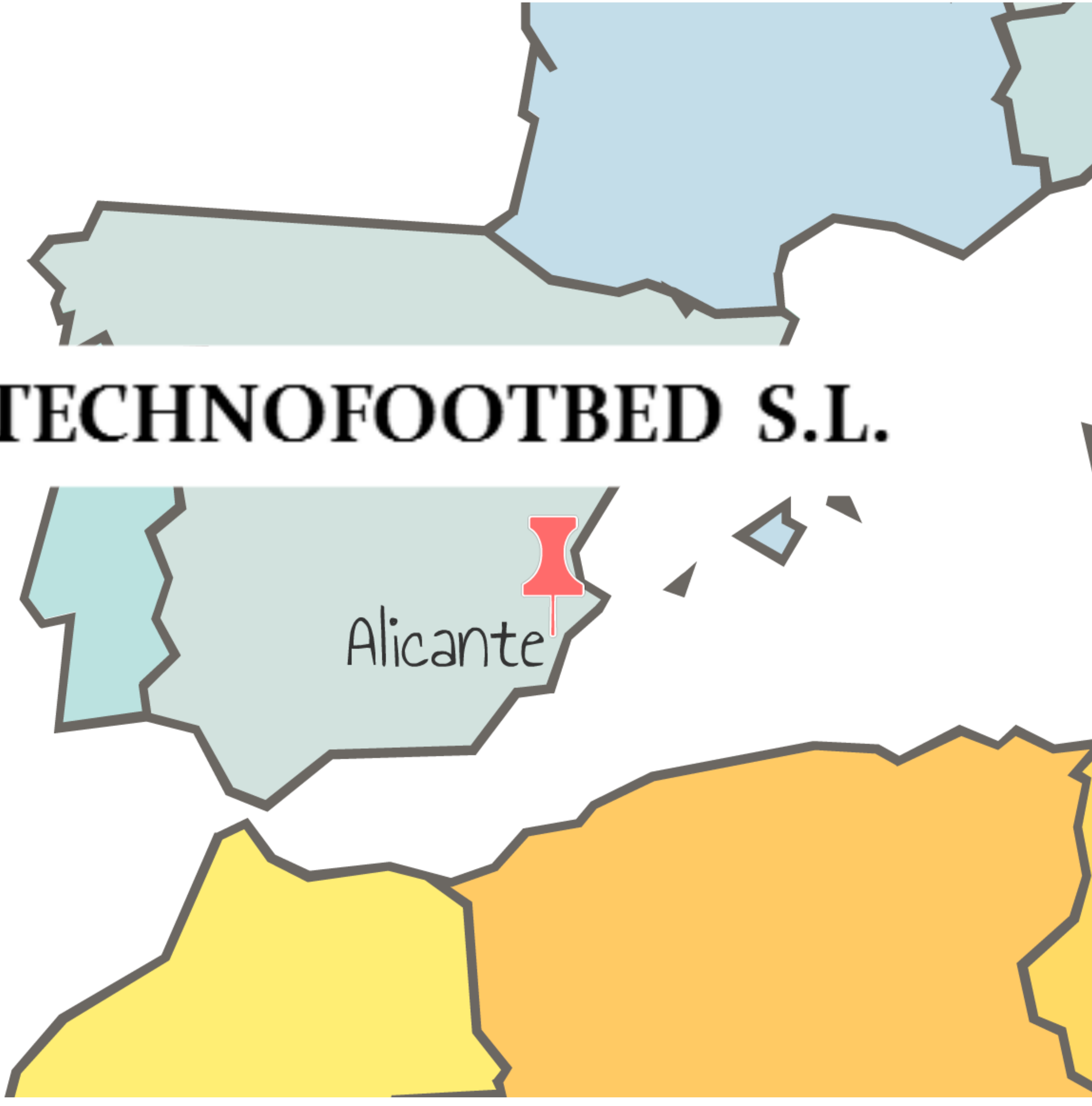
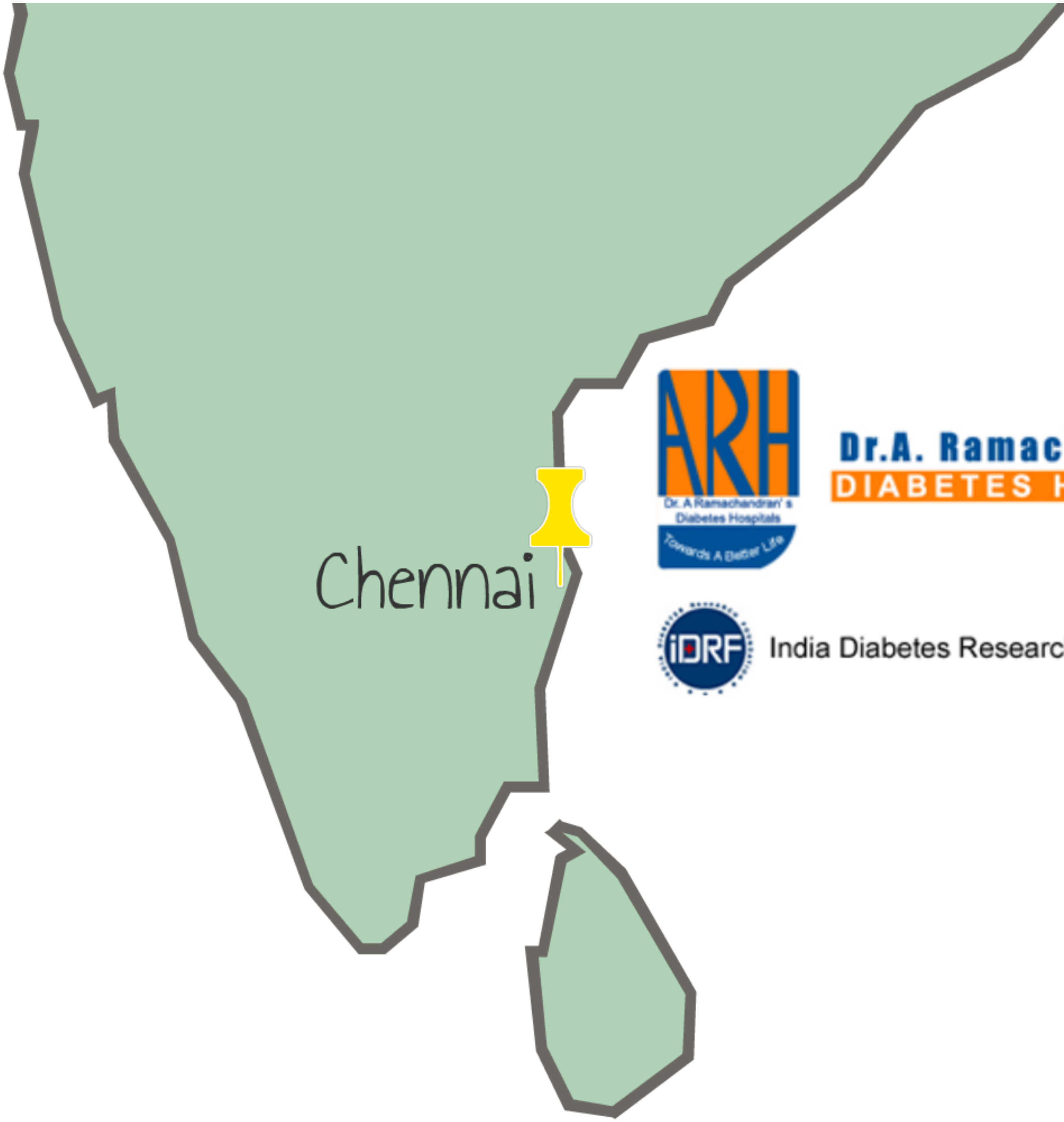
Magdeburg
h2
Hochschule
Magdeburg • Stendal
step
OGY THAT'S A STEP AHEAD

TECHNOFOOTBED S.L.



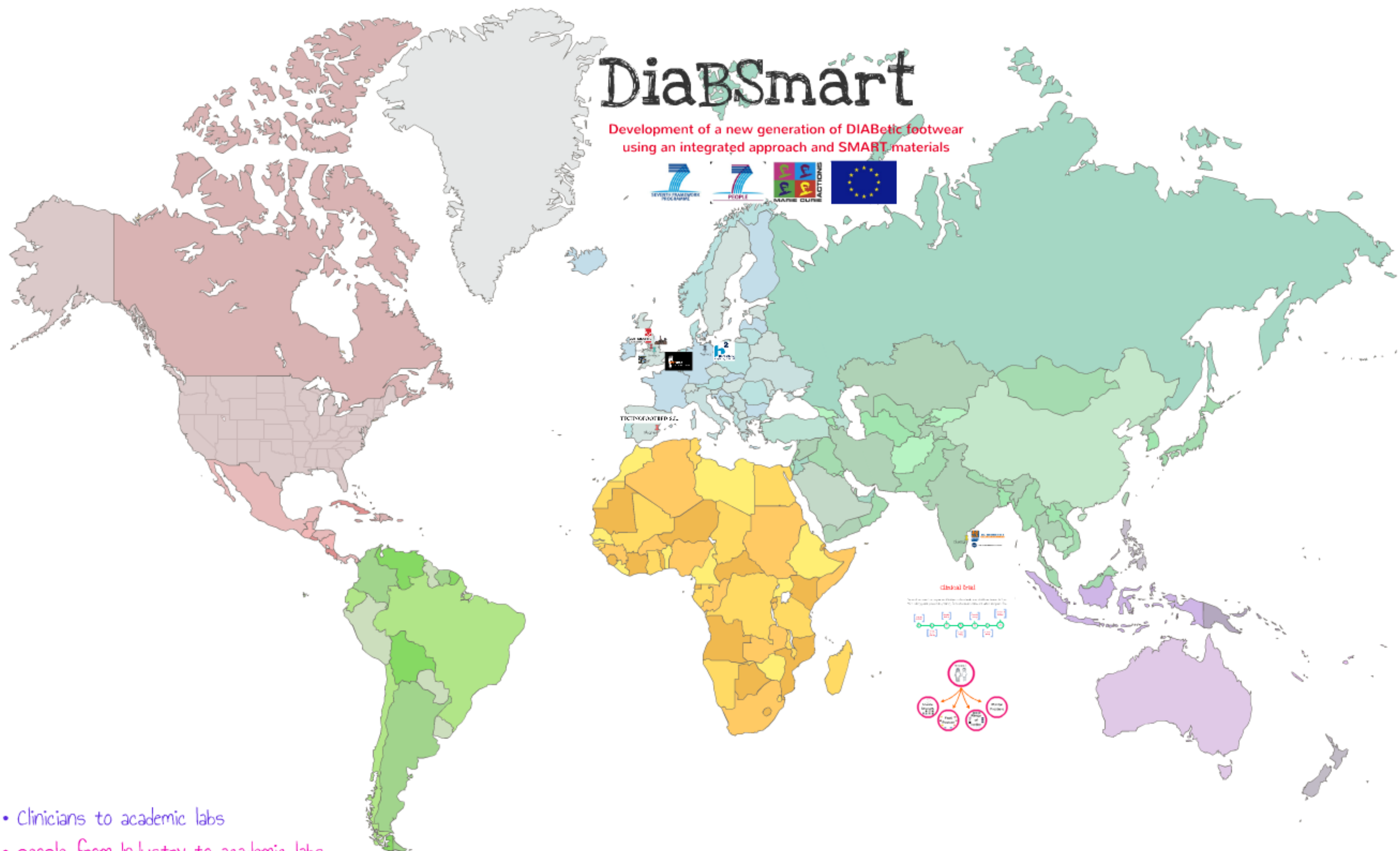


Dr.A. Ramachandran's
DIABETES HOSPITALS

India Diabetes Research Foundation

DiaBSmart

Development of a new generation of DIABetic footwear using an integrated approach and SMART materials



- Clinicians to academic labs
- people from Industry to academic labs
- Academic researchers to clinics and industry

IDF DIABETES ATLAS

5th edition | 2012 update

International Diabetes Federation

Why Diabetic Foot!

400 million people in the world live with diabetes. A lost leg due to diabetes somewhere in the world every 20 seconds!

552 million people live with Diabetes by 2030! Increase due to ageing population, low physical activity, obesity and diet.

75 Million people worldwide will be requiring special foot care by 2030.

One of the most serious and costly complications of diabetes is diabetic foot.

It costs UK economy £1 Billion a year !

NORTH AMERICA AND CARIBBEAN

- More healthcare dollars were spent on diabetes in this region than any other
- 1 in 10 adults in this region has diabetes

MIDDLE EAST AND NORTH AFRICA

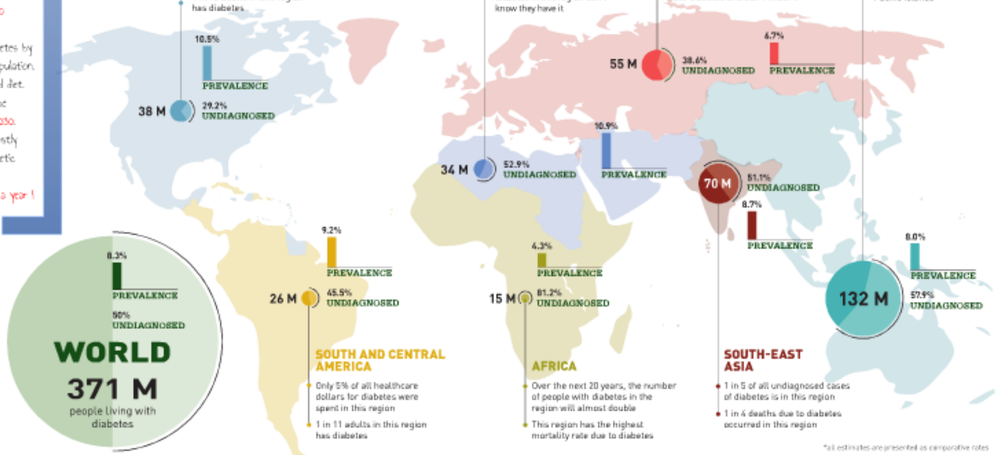
- 1 in 9 adults in this region has diabetes
- More than half of people with diabetes in this region don't know they have it

EUROPE

- 1 out of every 3 dollars spent on diabetes healthcare was spent in this region
- 21.2 million people in this region have diabetes and don't know it

WESTERN PACIFIC

- 1 in 3 adults with diabetes lives in this region
- 6 of the top 10 countries for diabetes prevalence are Pacific Islands



SOUTH AND CENTRAL AMERICA

- Only 5% of all healthcare dollars for diabetes were spent in this region
- 1 in 11 adults in this region has diabetes

AFRICA

- Over the next 20 years, the number of people with diabetes in the region will almost double
- This region has the highest mortality rate due to diabetes

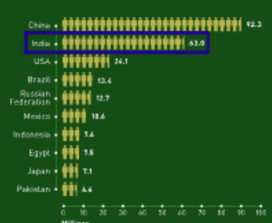
SOUTH-EAST ASIA

- 1 in 5 of all undiagnosed cases of diabetes is in this region
- 1 in 4 deaths due to diabetes occurred in this region

*all estimates are presented as comparative rates

More than **371 million** people have diabetes.

TOP 10 COUNTRIES/TERRITORIES FOR PEOPLE WITH DIABETES (20-79 YEARS)



The number of people with diabetes is **increasing** in every country.

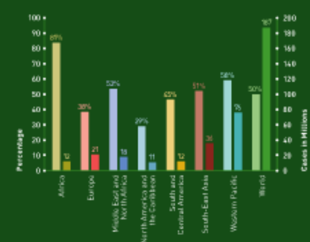
TOP 10 COUNTRIES/TERRITORIES FOR PREVALENCE* (%) OF DIABETES (20-79 YEARS)

COUNTRY /TERRITORY	PREVALENCE (%)
1 Federated States of Micronesia	37.2
2 Nauru	30.1
3 Marshall Islands	27.1
4 Kiribati	25.5
5 Tuvalu	24.8
6 Kuwait	23.9
7 Saudi Arabia	23.4
8 Qatar	23.3
9 Bahrain	22.4
10 Vanuatu	22.0

*comparative prevalence

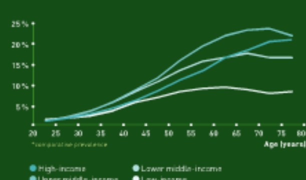
Half of people with diabetes **don't know** they have it.

UNDIAGNOSED PERCENTAGE AND UNDIAGNOSED CASES OF DIABETES (20-79 YEARS) BY REGION



4 out of 5 people with diabetes live in **low- and middle-income** countries.

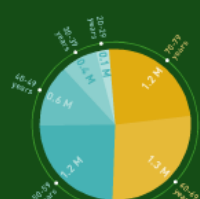
PREVALENCE* (%) ESTIMATES OF DIABETES (20-79 YEARS) BY INCOME GROUP AND AGE



*comparative prevalence

Half of people who die from diabetes are **under the age of 60**.

DEATHS ATTRIBUTABLE TO DIABETES BY AGE (20-79 YEARS)



4.8 million people **died** and **471 billion USD** were **spent** due to diabetes in 2012.

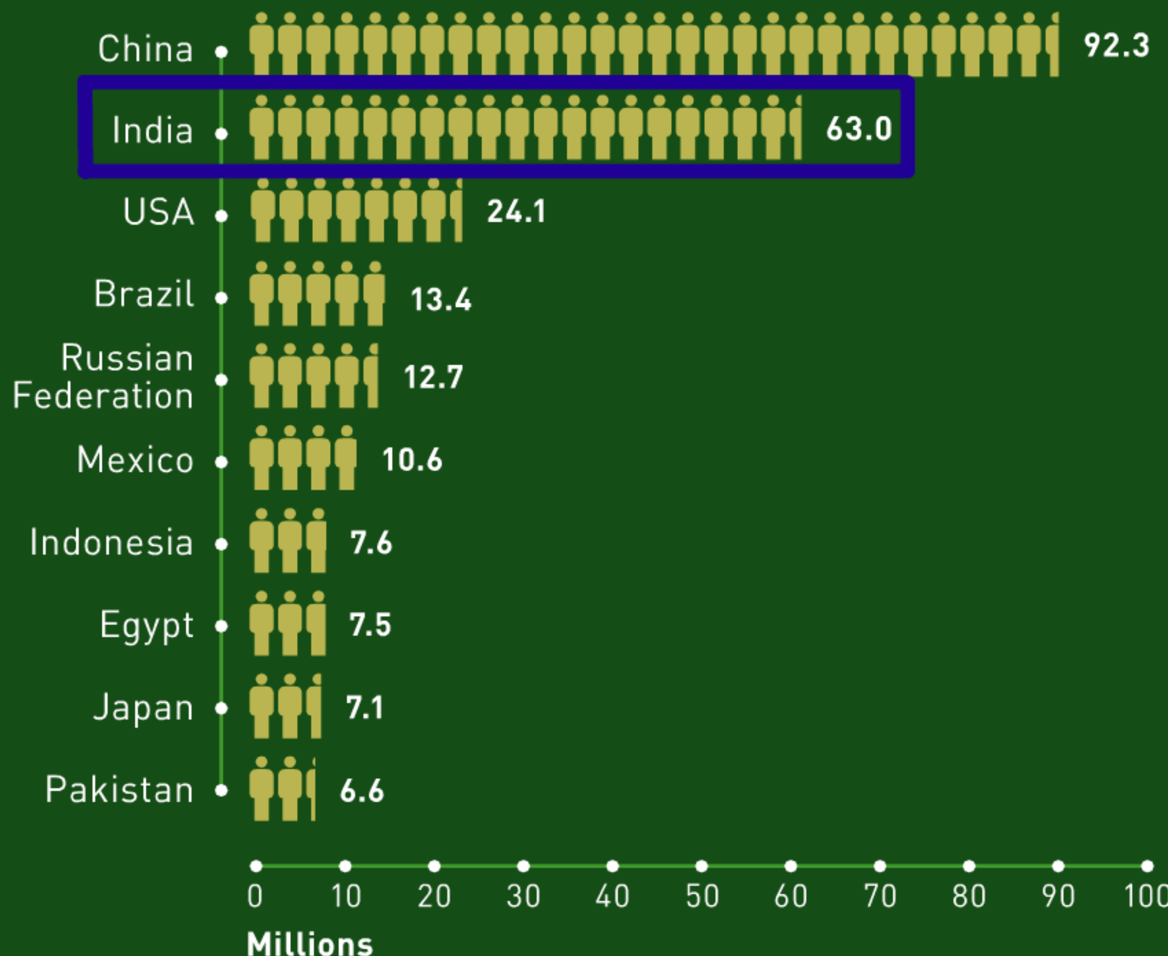
HEALTHCARE EXPENDITURES AND DEATHS PER 1,000 DUE TO DIABETES BY INCOME GROUP

CORPORATE SPONSORS | IDF would like to express its thanks to the following sponsors for their generous support of this update of the IDF Diabetes Atlas:

www.idf.org/diabetesatlas

More than **371 million** people have diabetes.

TOP 10 COUNTRIES/TERRITORIES FOR PEOPLE WITH DIABETES (20-79 YEARS)



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TOP 10 COU
OF DIABETE

COUNTRY /
1 Federated
2 Nauru
3 Marshall I
4 Kiribati
5 Tuvalu
6 Kuwait
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9 Bahrain
10 Vanuatu

*comparative prev

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One of the most serious and costly complications of diabetes is diabetic foot.

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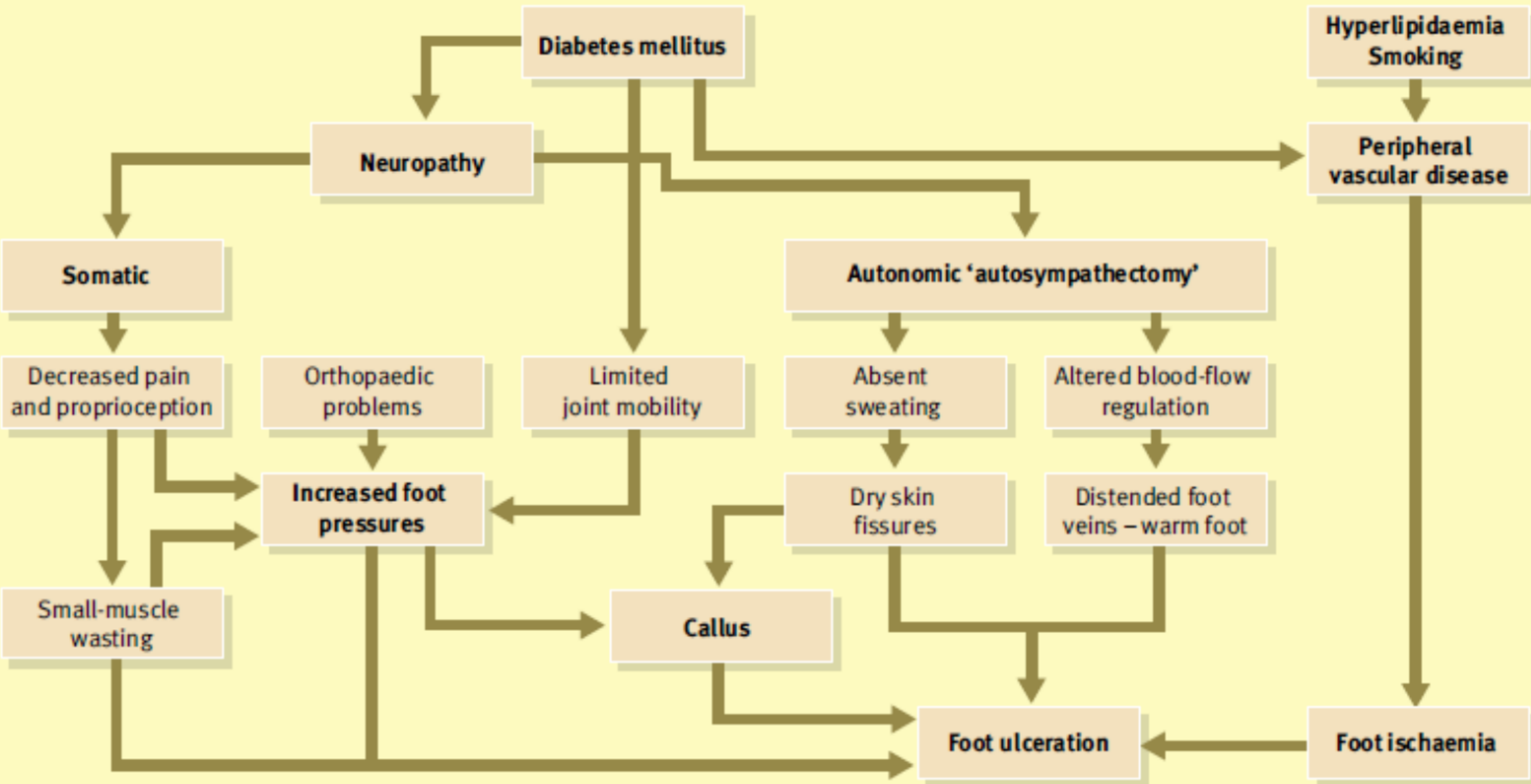
Pathways to diabetic foot ulceration



Source: Boulton A J M. *Diabetic Med* 1996; **3:** (Suppl. 1).

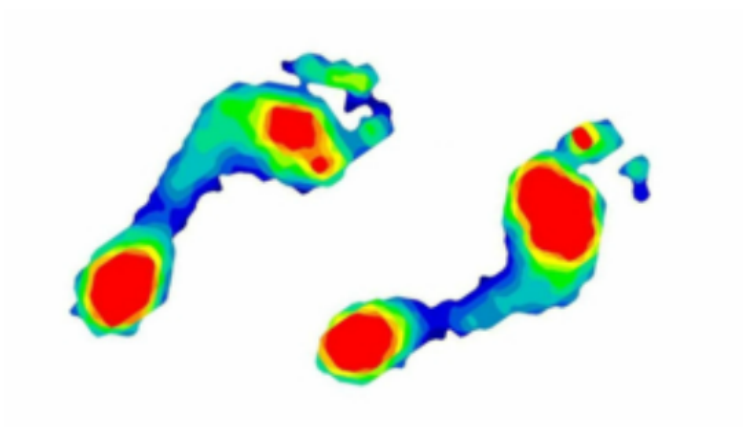
It has been well established that the majority of injuries to the foot (ulcers) are a result of mechanical trauma that the patient does not recognise because of Neuropathy.

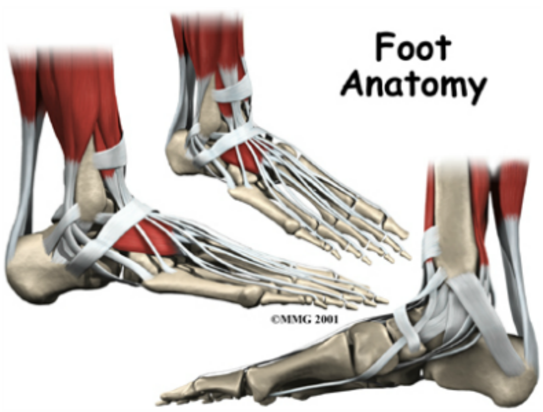
(Cavanagh and Ulbrecht, 2006)

Gaps in Diabetic Foot Biomechanics research

- Is measurement of peak plantar pressure enough?
- The effect of Limited joint mobility
- Foot as a multisegment model
- Orthotics/footwear still based on clinician's empirical opinion
- The way forward.....

Spenser (2000) Cochrane Database of Systematic Reviews (3): CD002302





...... Gaps in Diabetic Footwear Literature ?

Systematic review

Contents lists available at SciVerse ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors associated with diabetic foot ulceration: A systematic review☆

Aoife Healy *, Roozbeh Naemi, Nachiappan Chockalingam

CSHER, Faculty of Health Sciences, Staffordshire University, Stoke on Trent, ST4 2DF, United Kingdom

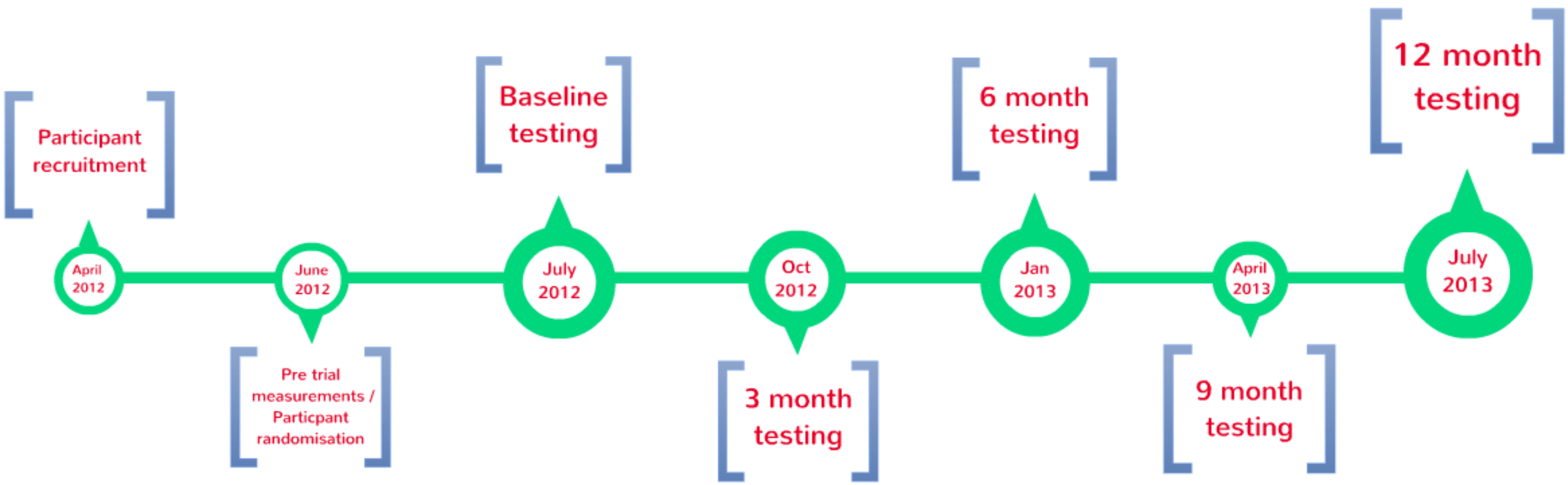
While the use of custom orthotic insoles in plantar pressure reduction is supported in cross sectional studies, longitudinal studies are required to confirm their benefit.

No research to date has examined the effectiveness of footwear in preventing ulceration.

Clinical Trials

Clinical trial

The aim of the study is to compare the effectiveness of two insoles made of different materials (MCP and PU) in reducing plantar pressure and preventing foot ulcerations in patients with diabetic neuropathic foot.



- The objective was to assess the effect of footwear on the ulceration risk factors:
- (1) Neurological
- (2) Vascular
- (3) Physiological
- (4) Biomechanical
    - Plantar pressure (Barefoot and Inshoe)
    - foot type
    - Ankle strength
    - Range of motion
    - Balance.

Pre trial measurements

- Duration of diabetes
- HbA1c
- Age
- VPT
- Monofiliament
- Visual acuity
- Fasting blood glucose
- Serum creatinine
- Doppler
- Biothesiometry
- Nerve conduction velocity

Ramdomisation

Criteria	0	1
Duration of diabetes (years)	0-10	Over 10
HbA1c	Good to fair control	Poor control
Age (years)	18 - 45	46 - 80
VPT (V)	25 - 40	Over 40
Monofilament	Partial loss (4 or less sites)	Complete loss
ABI	0.9 - 1.2	<0.8 or>1.2
Visual acuity	Normal, no NPDR	Acuity less than 6 or evidence of retinopathy

Naemi et al., J Clin Trials 2013, 4:1
http://dx.doi.org/10.4172/2167-0870.1000150

Clinical Trials

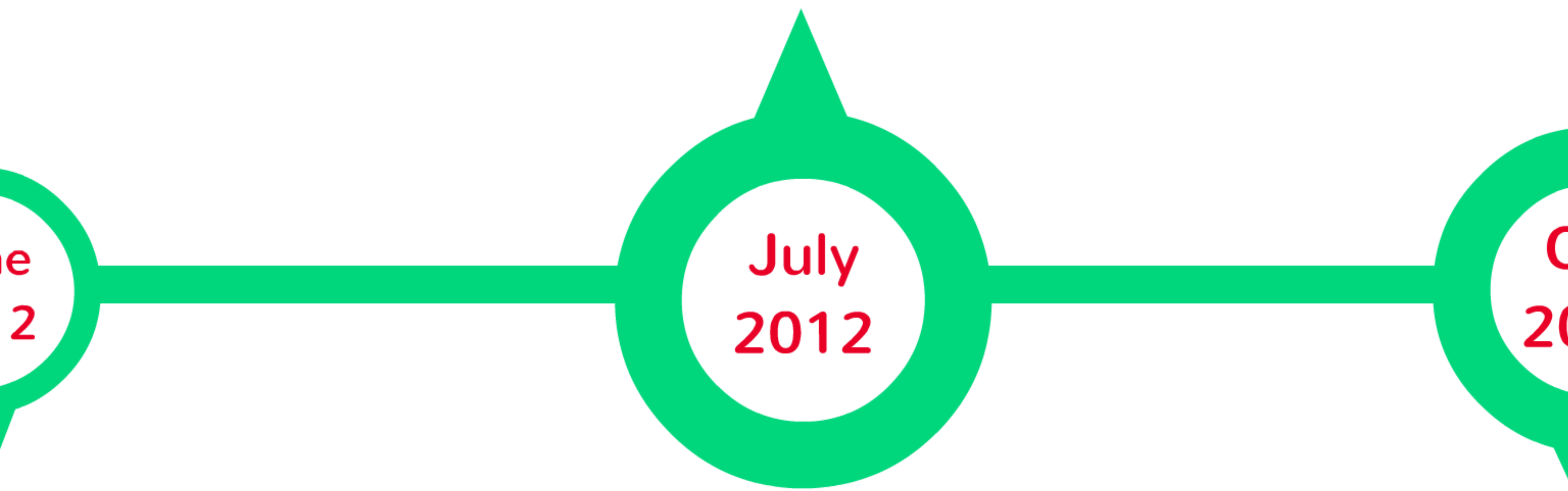
Research Article Open Access

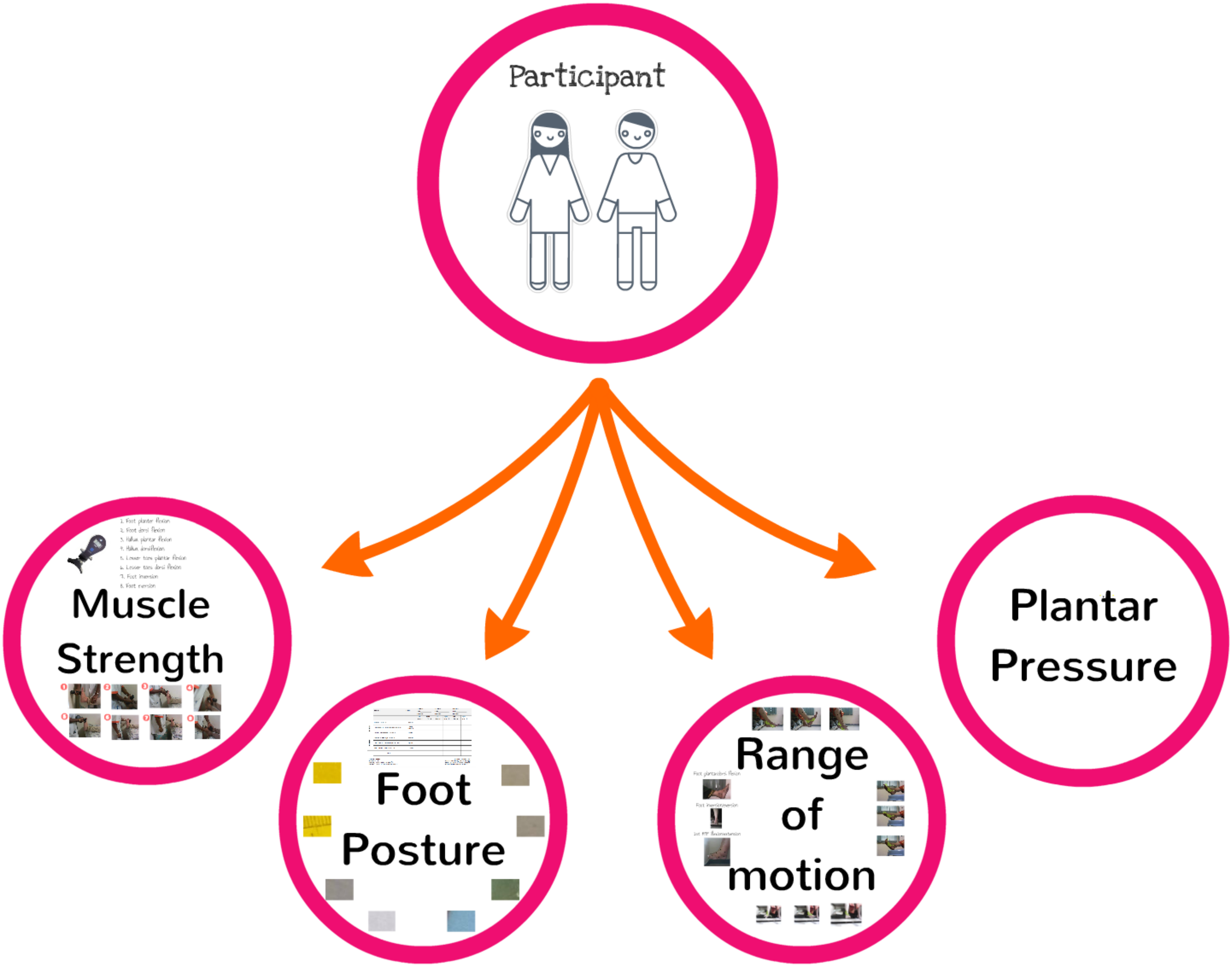
A Combined Technique for Randomisation of a Small Number of Participants with a Variety of Covariates into Treatment and Control Groups in Randomised Controlled Trials

Roozbeh Naemi[1,*], Aoife Healy[1], Lakshmi Sundar[2], Ambadi Ramachandran[2] and Nachiappan Chockalingam[1]

[1]*Staffordshire University, Stoke on Trent, Staffordshire, UK*
[2]*AR Diabetes Hospitals, Chennai, Tamil Nadu, India*

[Baseline testing]




Participant
1. Foot planter flexion
2. Foot dorsi flexion
3. Hallux plantar flexion
4. Hallux dorsiflexion
5. Lesser toes plantar flexion
6. Lesser toes dorsi flexion
7. Foot inversion
8. Foot eversion
Muscle Strength
Foot Posture
Range of motion
Plantar Pressure

1. Foot planter flexion
2. Foot dorsi flexion
3. Hallux plantar flexion
4. Hallux dorsiflexion
5. Lesser toes plantar flexion
6. Lesser toes dorsi flexion
7. Foot inversion
8. Foot eversion

Muscle Strength

	FACTOR	PLANE	SCORE 1 Date______ Comment______		SCORE 2 Date______ Comment______		SCORE 3 Date______ Comment______	
			Left -2 to +2	Right -2 to +2	Left -2 to +2	Right -2 to +2	Left -2 to +2	Right -2 to +2
Rearfoot	Talar head palpation	Transverse						
	Curves above and below the lateral malleolus	Frontal/ transverse						
	Inversion/eversion of the calcaneus	Frontal						
Forefoot	Prominence in the region of the TNJ	Transverse						
	Congruence of the medial longitudinal arch	Sagittal						
	Abd/adduction forefoot on rearfoot	Transverse						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to -4, Highly supinated -5 to -12


Foot


Posture






Range of motion

Foot plantar/dorsi flexion

Foot inversion/eversion

1st MTP flexion/extension

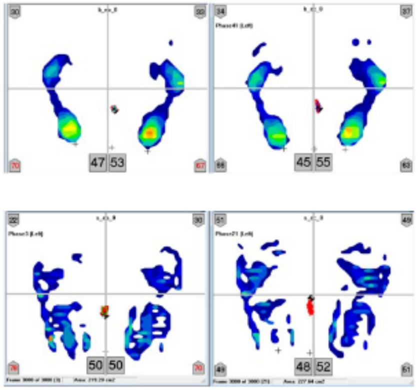




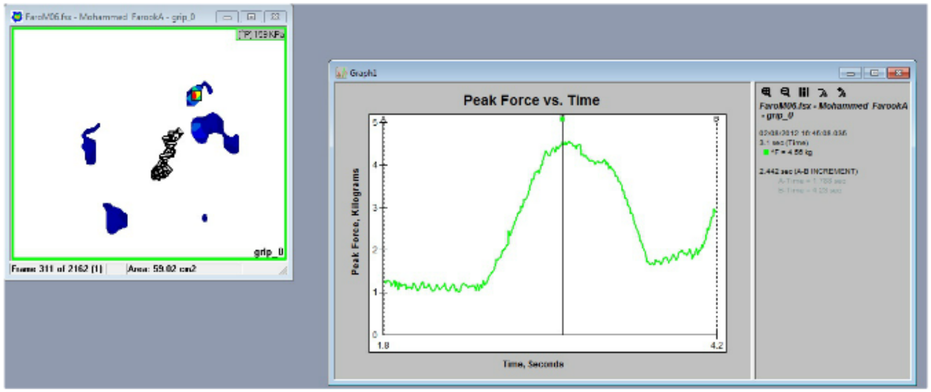
Plantar Pressure

MatScan

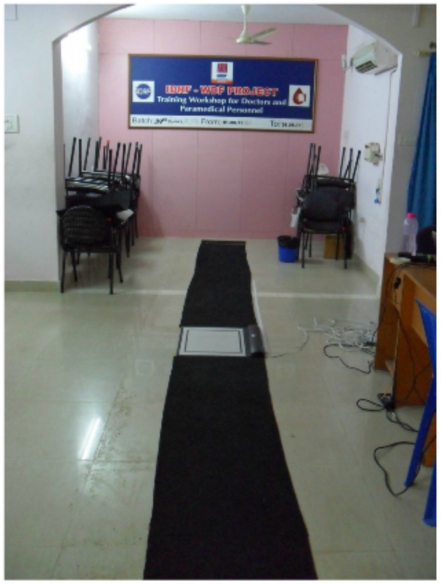
Balance (Romberg test)



Paper grip test

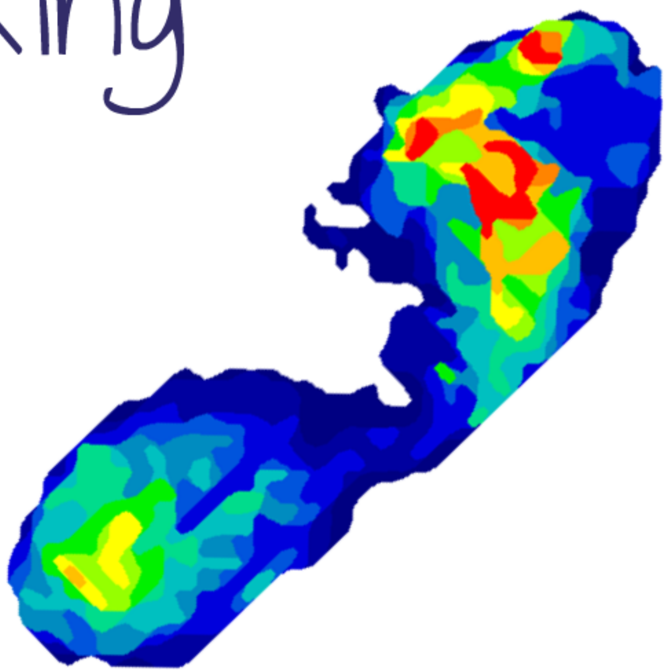


Barefoot walking



F-Scan

In shoe pressure during walking



Clinical trial

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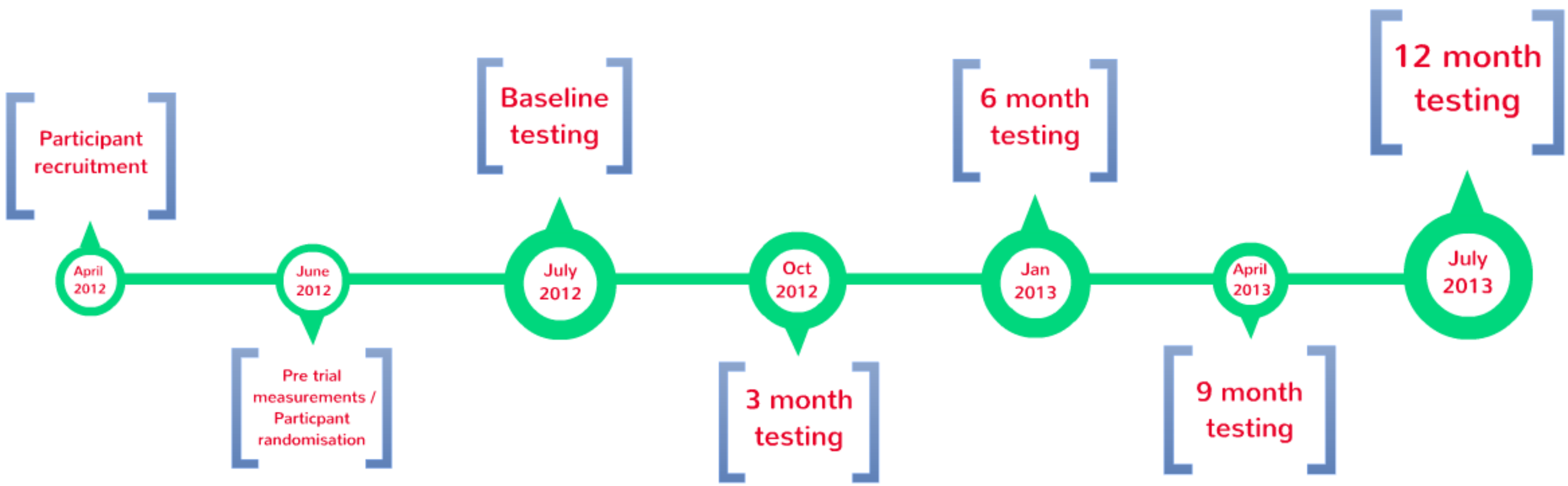

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
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Development and Testing of a New Generation of Diabetic Footwear (DiaBSmart)

This study is currently recruiting participants.

Verified April 2013 by Staffordshire University

Sponsor:
Staffordshire University

Collaborator:
India Diabetes Research Foundation & Dr. A. Ramachandran's Diabetes Hospitals

Information provided by (Responsible Party):
Nachiappan Chockalingam, Staffordshire University

ClinicalTrials.gov Identifier:
NCT01816906

First received: March 14, 2013
Last updated: April 4, 2013
Last verified: April 2013
History of Changes

To identify the most suitable insole material that can reduce the ulceration risk an in-depth knowledge of mechanical behaviour of the plantar soft tissue under load was essential.

This requires quantifying soft tissue material properties and internal stress, which can only be achieved by combining Numerical, and Mathematical Analyses (Finite Element Method).

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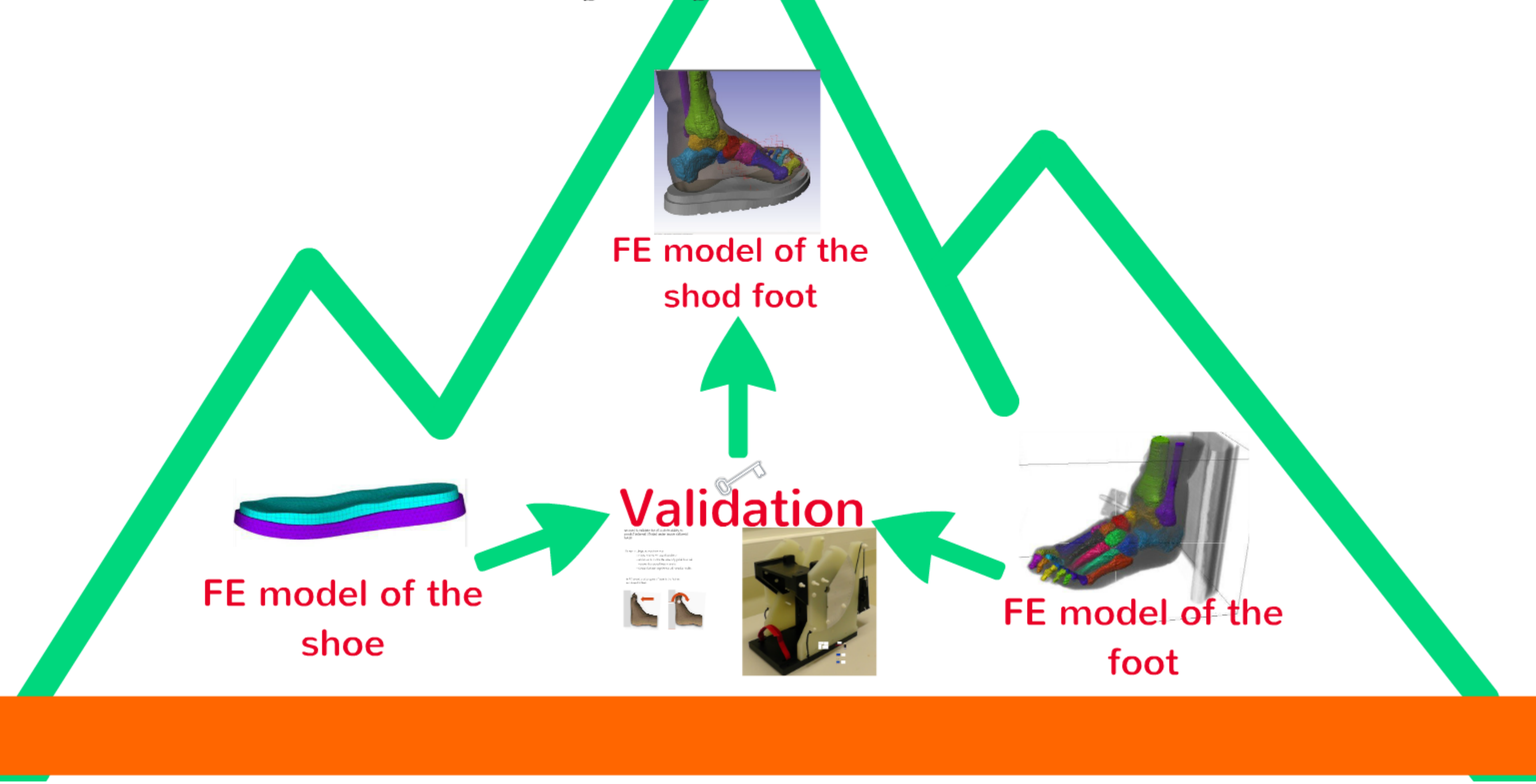
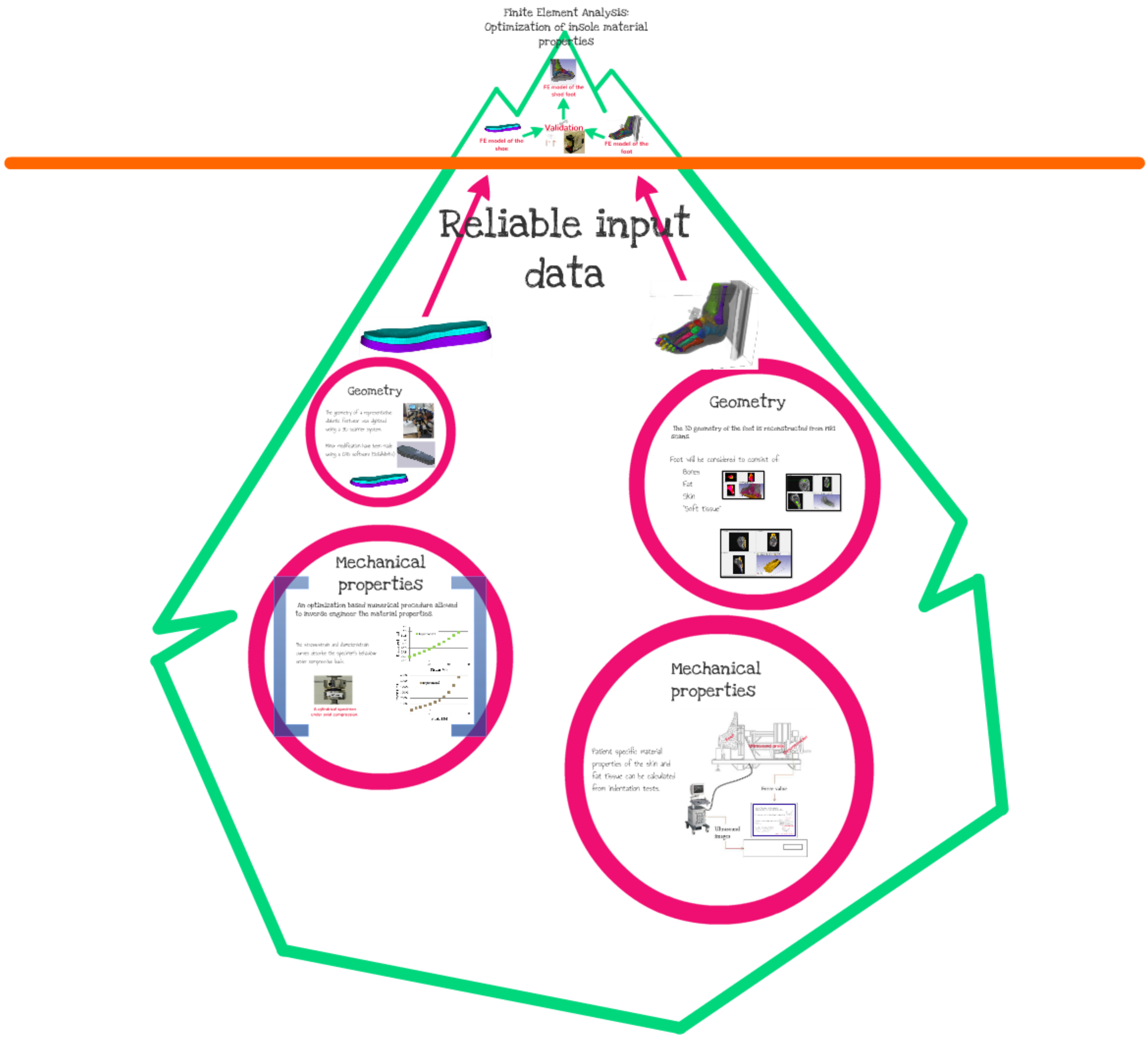
(Finite Element Method).

Finite Element Analysis: Optimization of insole material properties

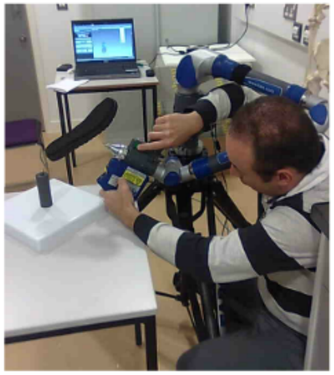




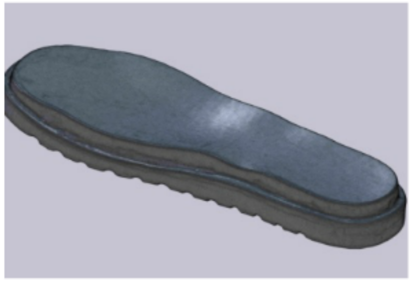
t stiffness.
properties

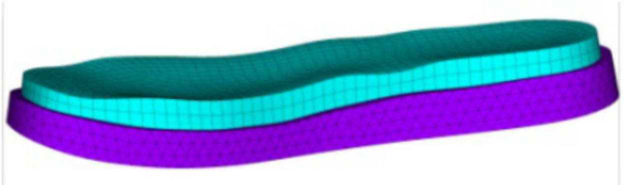
Geometry

The geometry of a representative diabetic footwear was digitized using a 3D scanner system.



Minor modification have been made using a CAD software (SolidWorks)

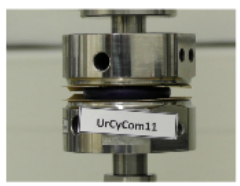




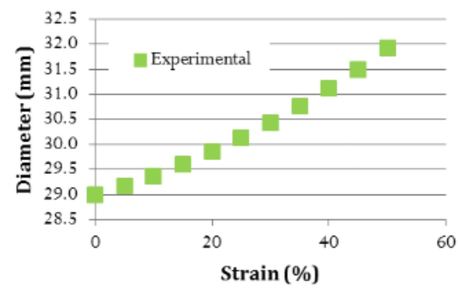
Mechanical properties

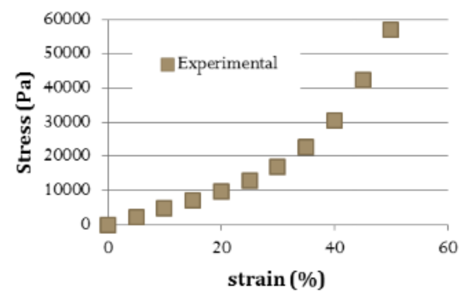
An optimization based numerical procedure allowed to inverse engineer the material properties.

The stress/strain and diameter/strain curves describe the specimen's behaviour under compressive loads.



A cylindrical specimen under axial compression.



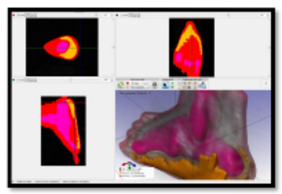


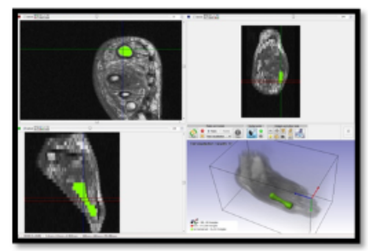
Geometry

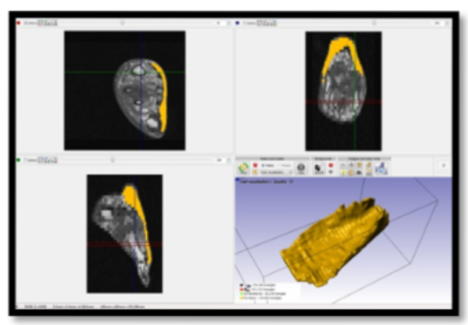
The 3D geometry of the foot is reconstructed from MRI scans.

Foot will be considered to consist of:

- Bones
- Fat
- Skin
- "Soft tissue"

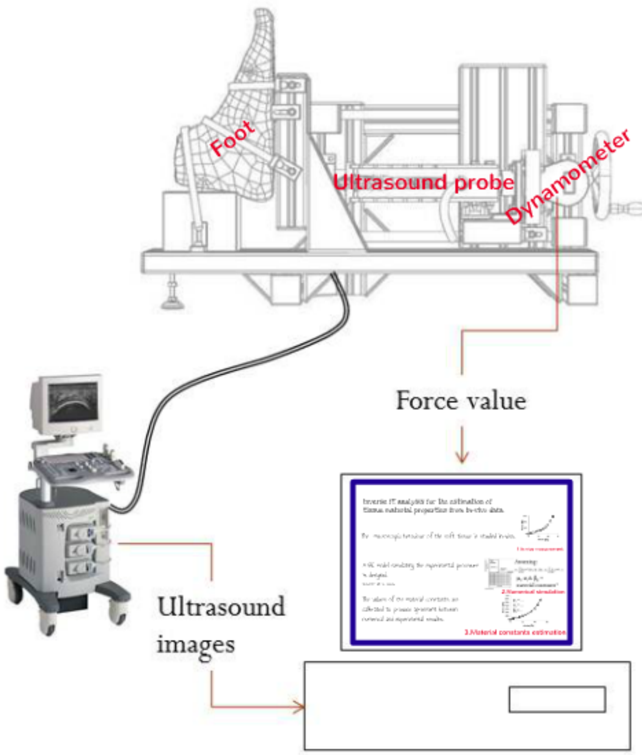


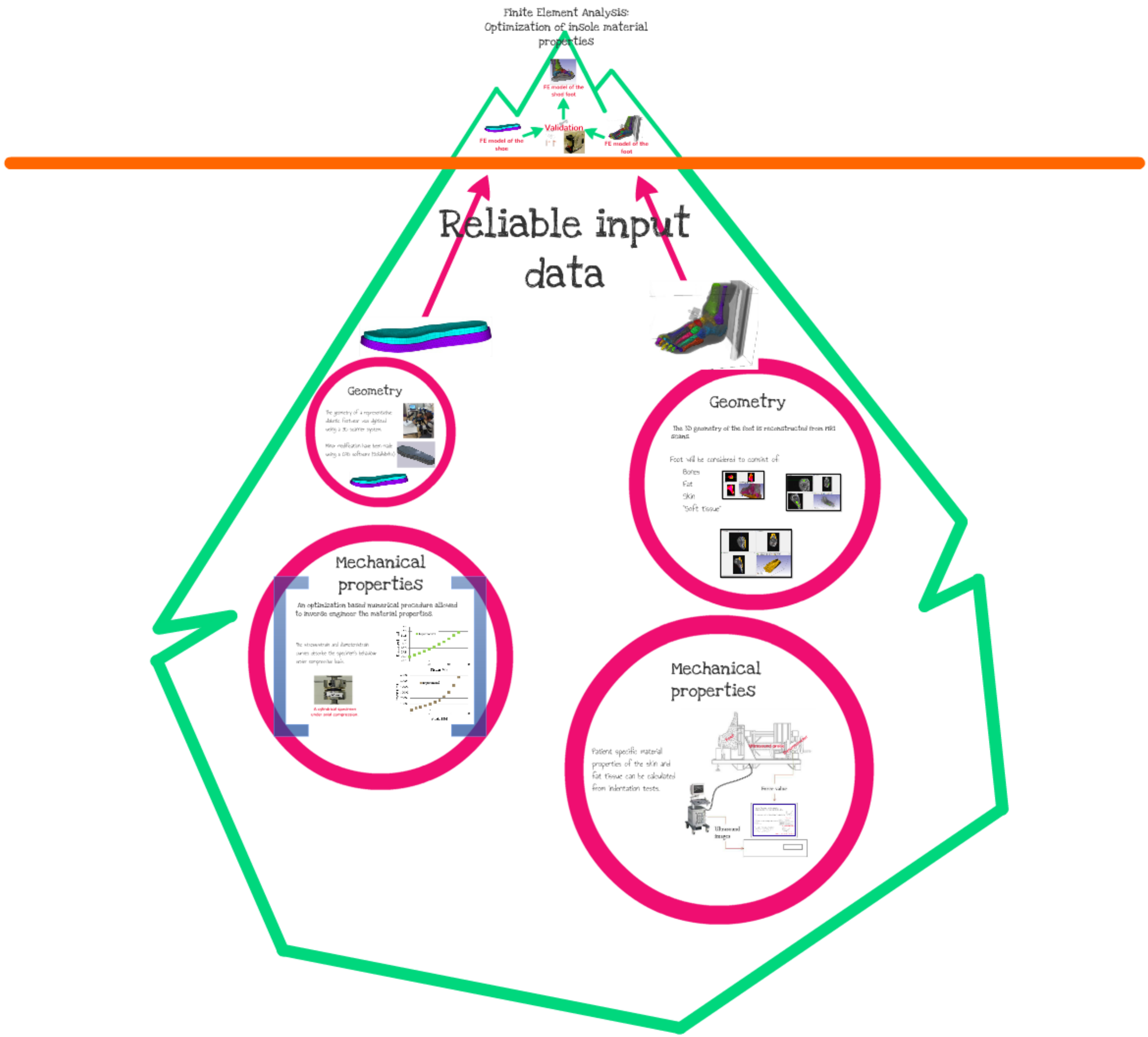




Mechanical properties

Patient specific material properties of the skin and fat tissue can be calculated from indentation tests.





t stiffness.
properties

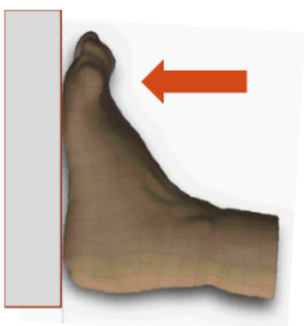
Validation

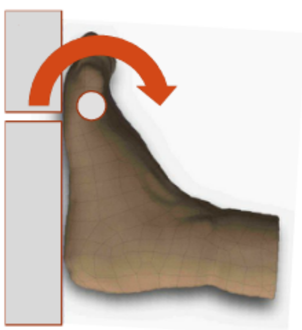
We need to validate the FE model's ability to predict internal strains under known external loads.

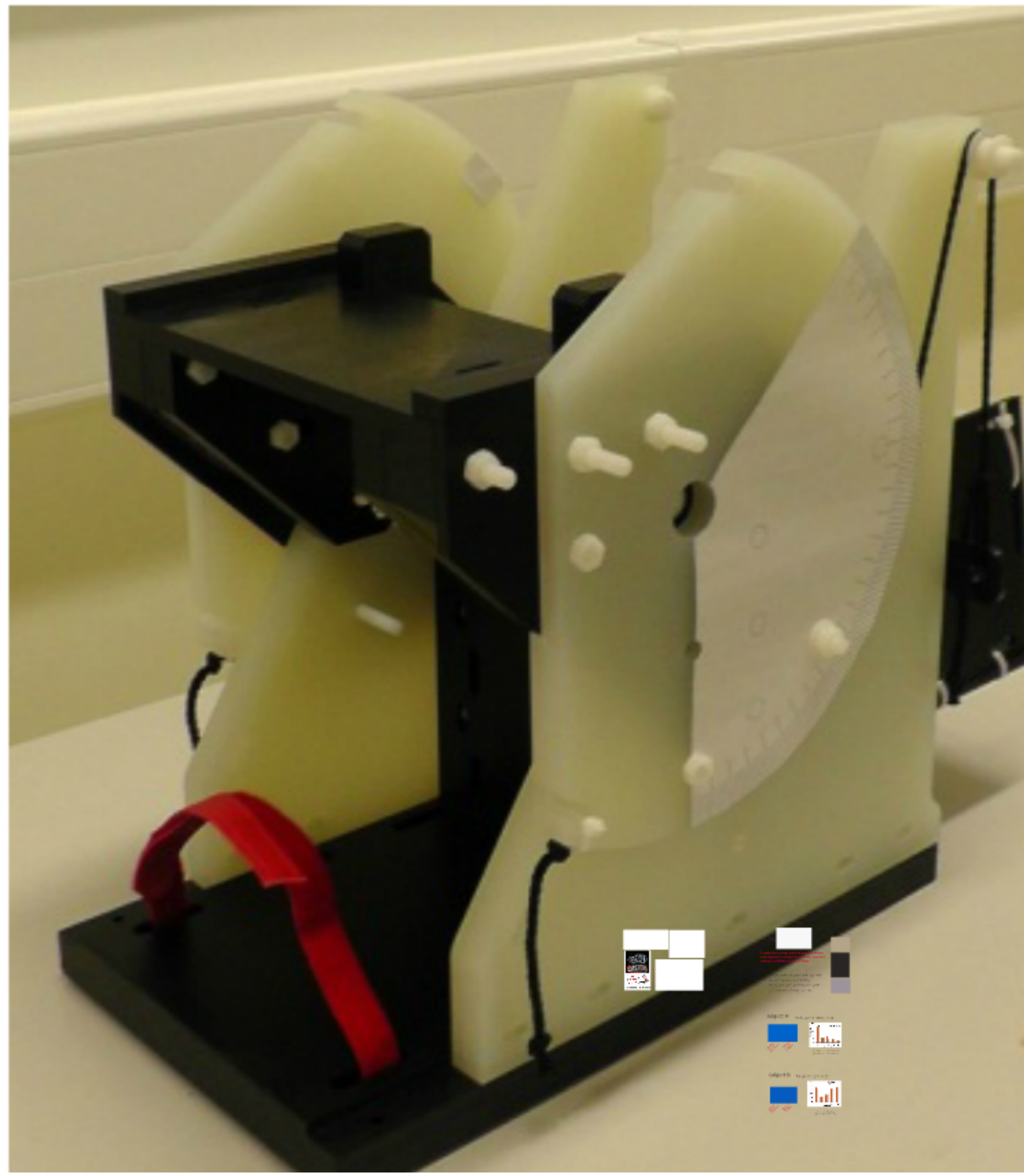
We need to design an experiment that:

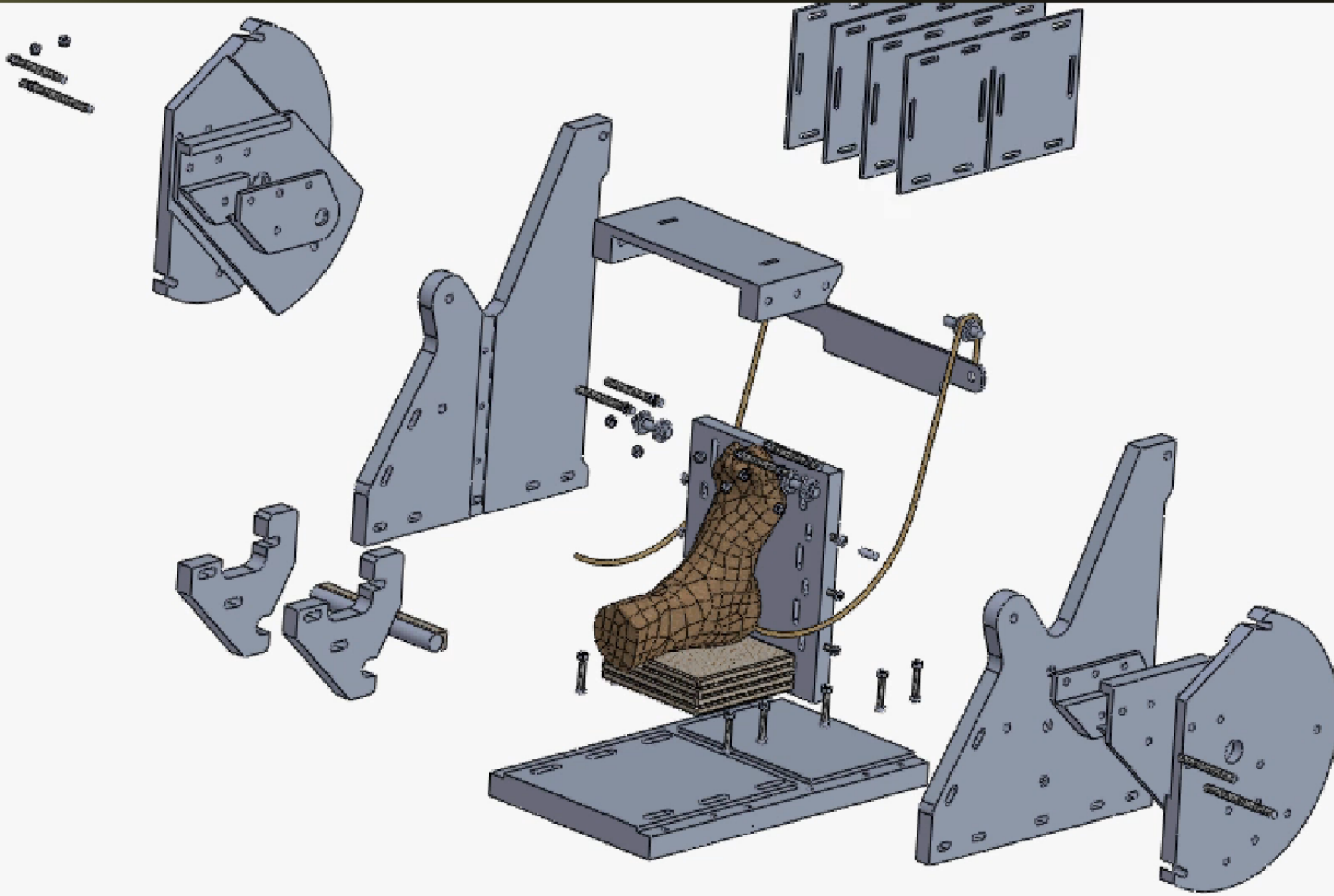
- Closely matches the desired simulation.
- enables us to control the externally applied loads and measure the resulted internal strains
- Compare between experimental and numerical results.

An MRI compatible device capable of loading to the foot has been designed and built.

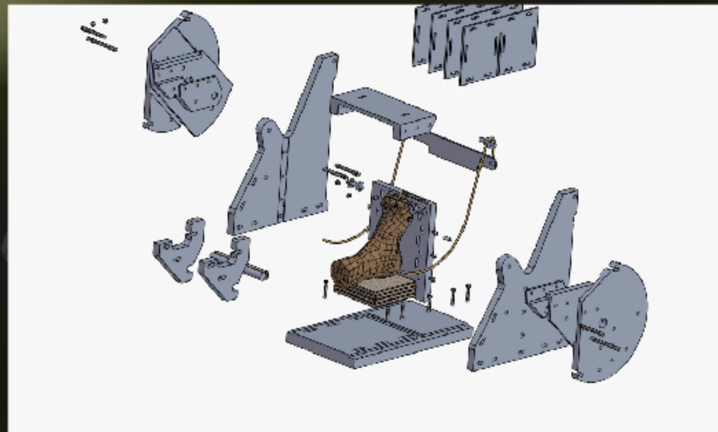




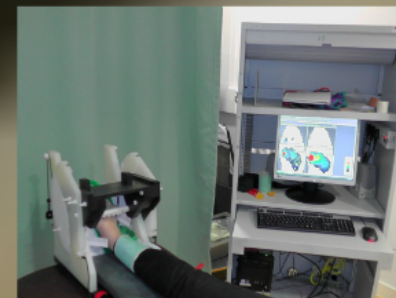


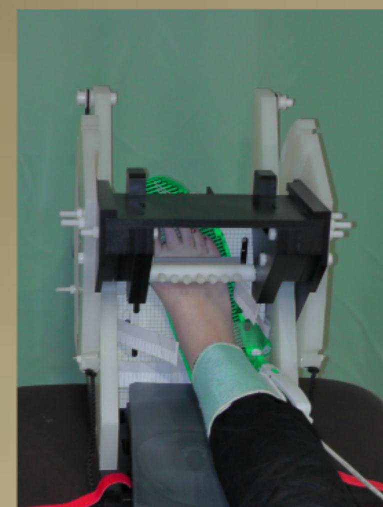


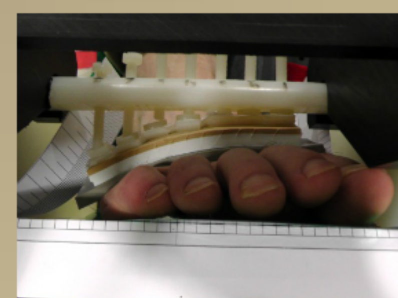
Pro



A preliminary study showed that the device was capable to reconstruct clinically relevant loading conditions of the forefoot.







The peak plantar pressure under each met-head was measured while standing.
The measured pressure distribution profile was reconstructed using our device.

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Technical note

An MRI compatible loading device for the reconstruction of clinically relevant plantar pressure distributions and loading scenarios of the forefoot

Panagiotis E. Chatzistergos*, Roozbeh Naemi, Nachiappan Chockalingam

CSHER, Faculty of Health Sciences, Staffordshire University, Stoke-on-Trent, United Kingdom

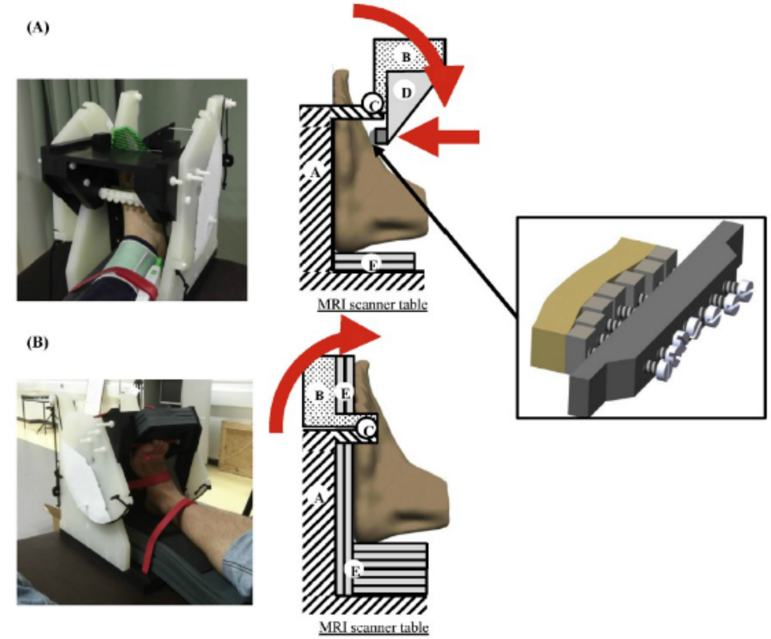


Fig. 1. Two different configurations of the MRI compatible loading device used to apply compressive (A) and bending loads (B). The punch used to apply the compressive load and to control its distribution is also shown.

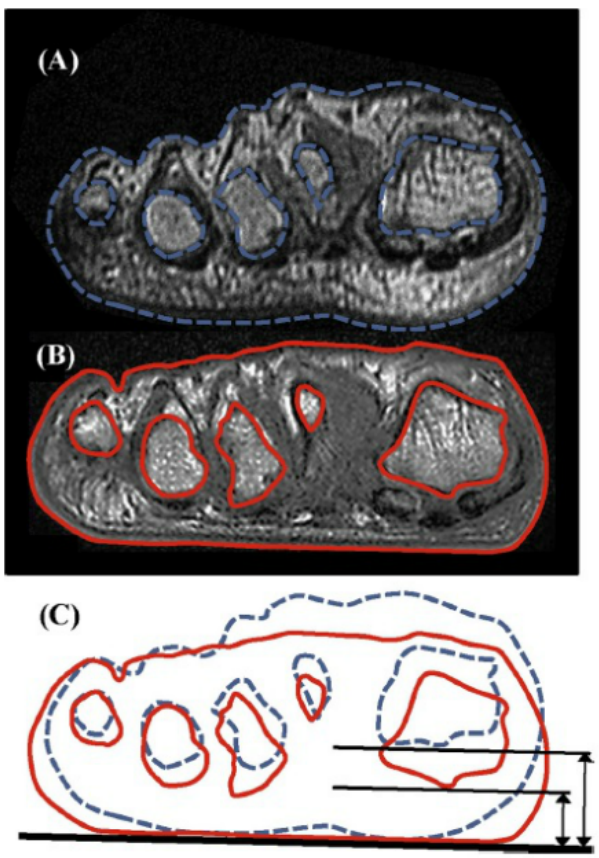


Fig. 2. MRI images of the forefoot before (A) and after compression (B). The boundaries of the foot and of the visible bones have been manually outlined for both cases (dotted blue and continuous red curves for A and B, respectively) and presented together (C) for comparison. (For interpretation of the references to color in this figure caption, the reader is referred to the web version of the article.)

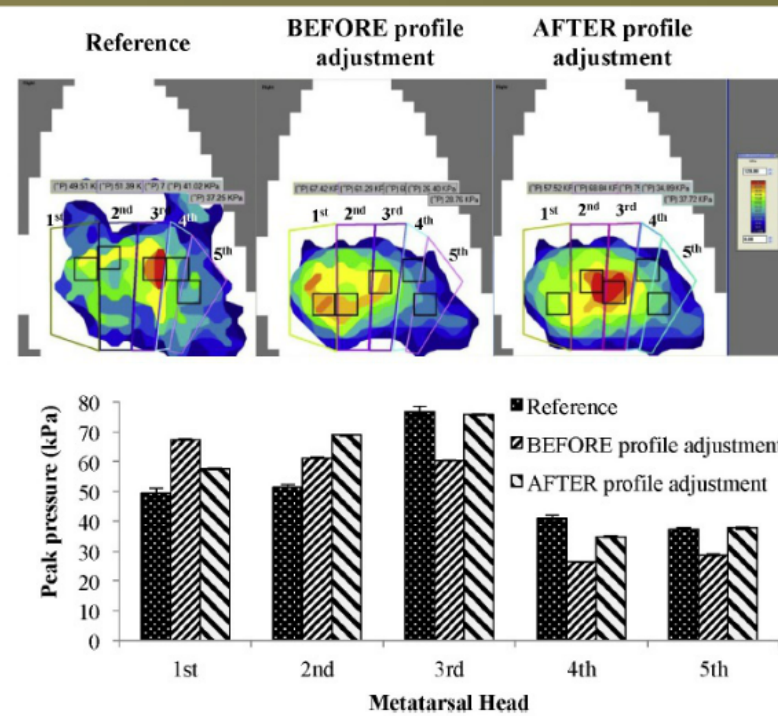
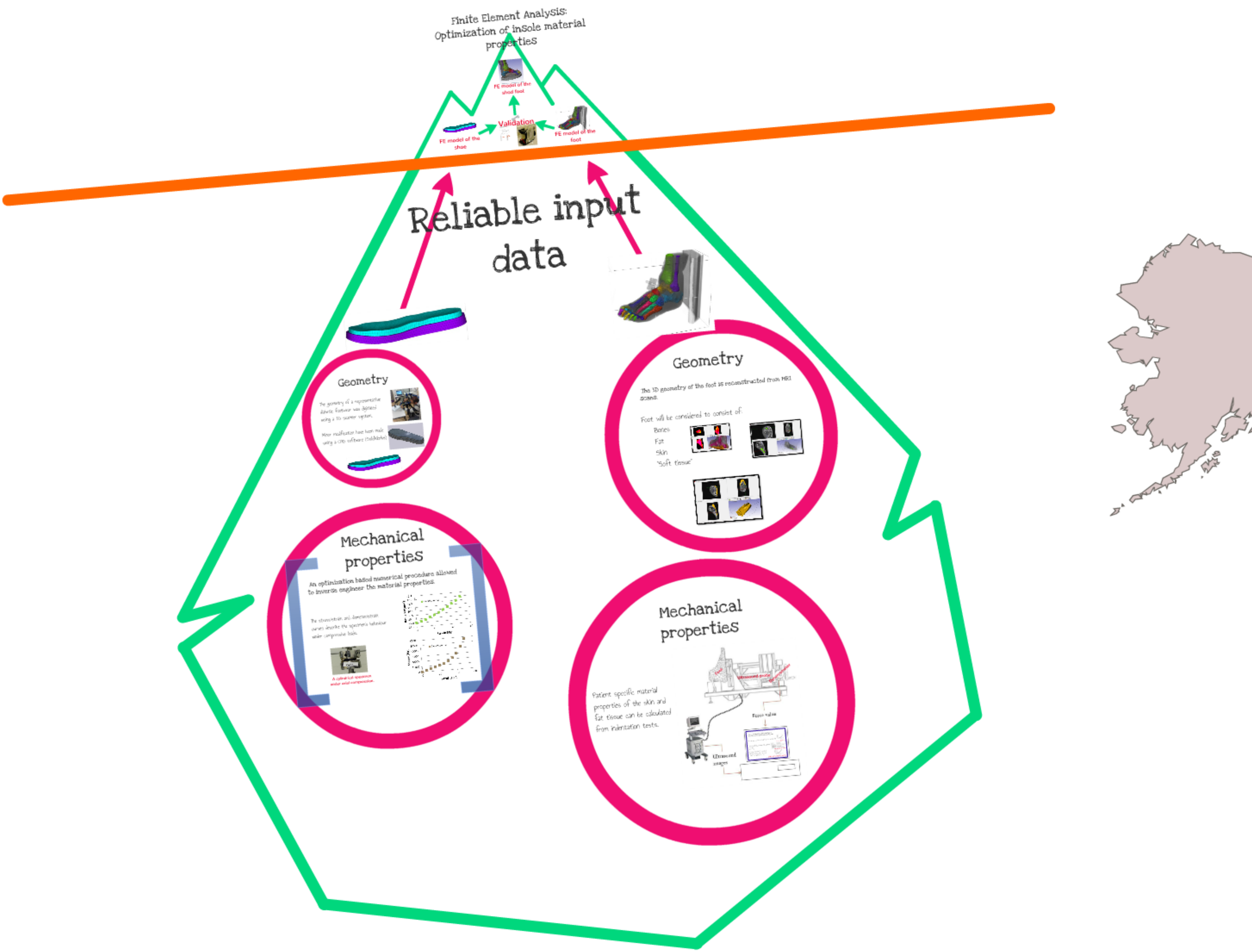
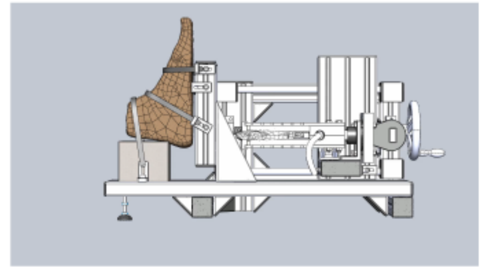


Fig. 3. The reference planar pressures (left) and the ones measured inside the device before (centre) and after (right) the adjustment of the compression punch profile for subject #6 (pressure in kP_a). The area of the MTHs is defined using a number of polygons. Inside each one of these polygons the location of peak pressure is marked by a rectangle. The average values of the peak pressures of each MTH are also plotted together for comparison.

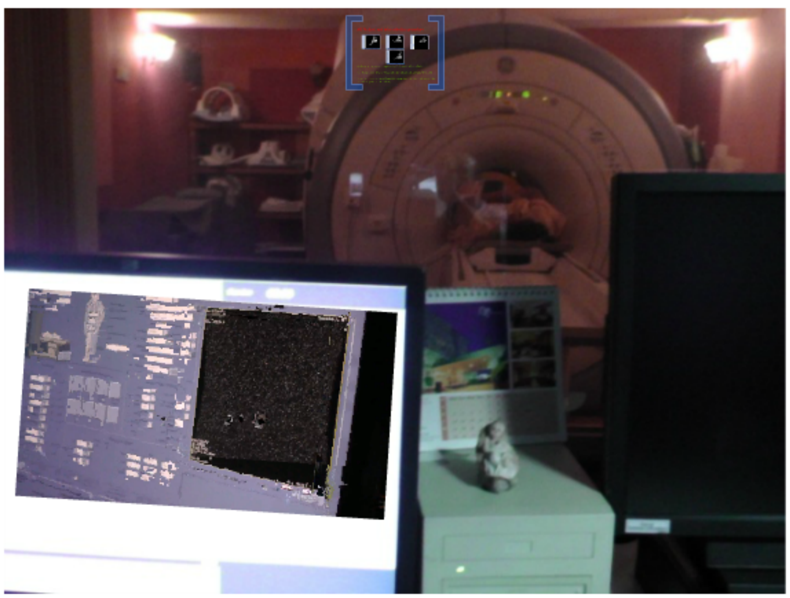


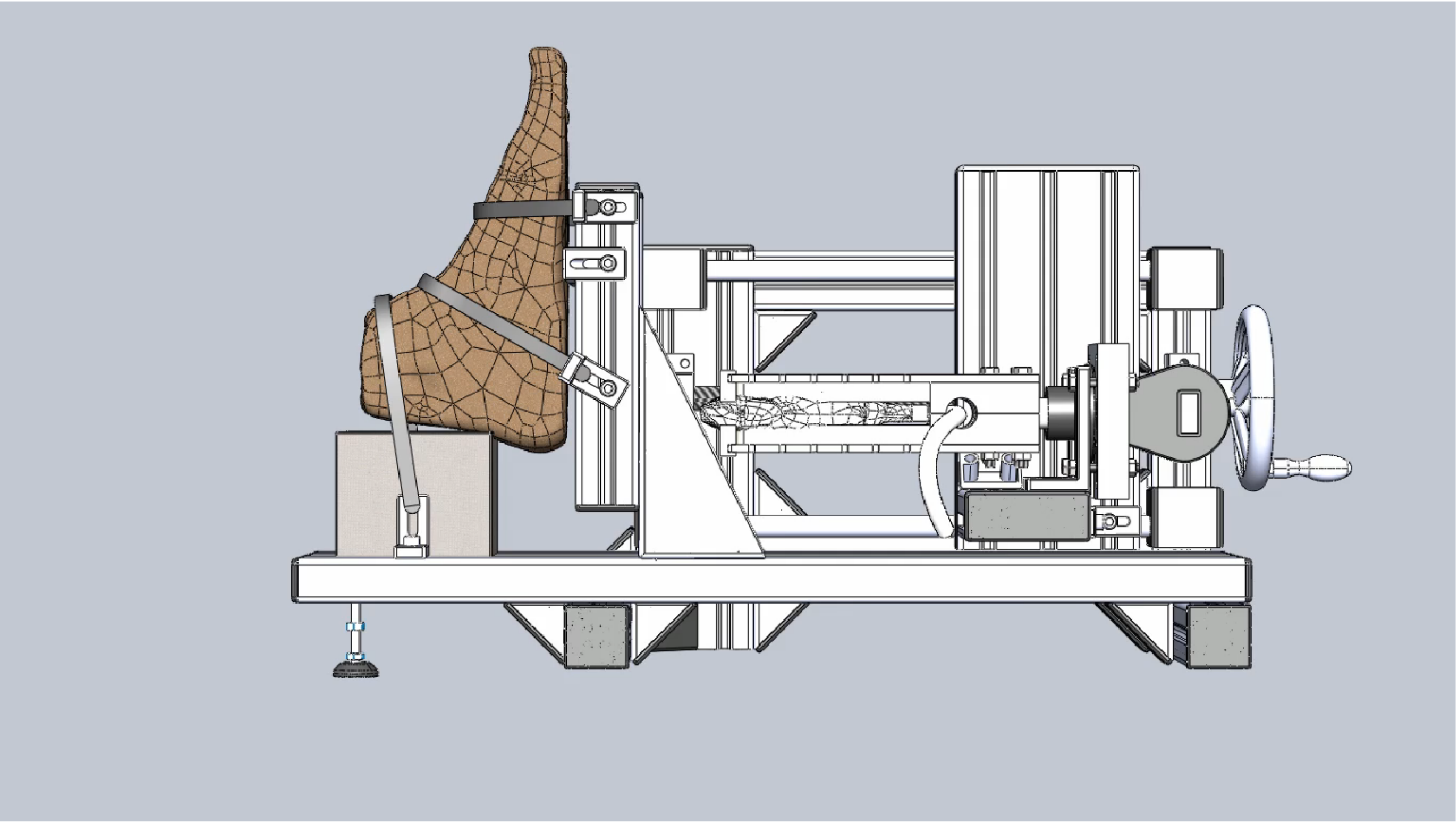
Finite Element Analysis: Optimization of insole material properties
FE model of the shod foot
Validation
FE model of the shoe
FE model of the foot
Reliable input data
Geometry
The geometry of a representative diabetic footwear was digitised using a 3D scanner system.
Minor modification have been made using a CAD software (SolidWorks)
Geometry
The 3D geometry of the foot is reconstructed from MRI scans.
Foot will be considered to consist of:
Bones
Fat
Skin
'Soft tissue'
Mechanical properties
An optimization based numerical procedure allowed to inverse engineer the material properties.
Mechanical properties
Patient specific material properties of the skin and fat tissue can be calculated from indentation tests.

imaging modalities



Two image modalities (MRI and Ultrasound) were identified to assess the plantar soft tissue behaviour under load.





UltraSound Indentation Technique

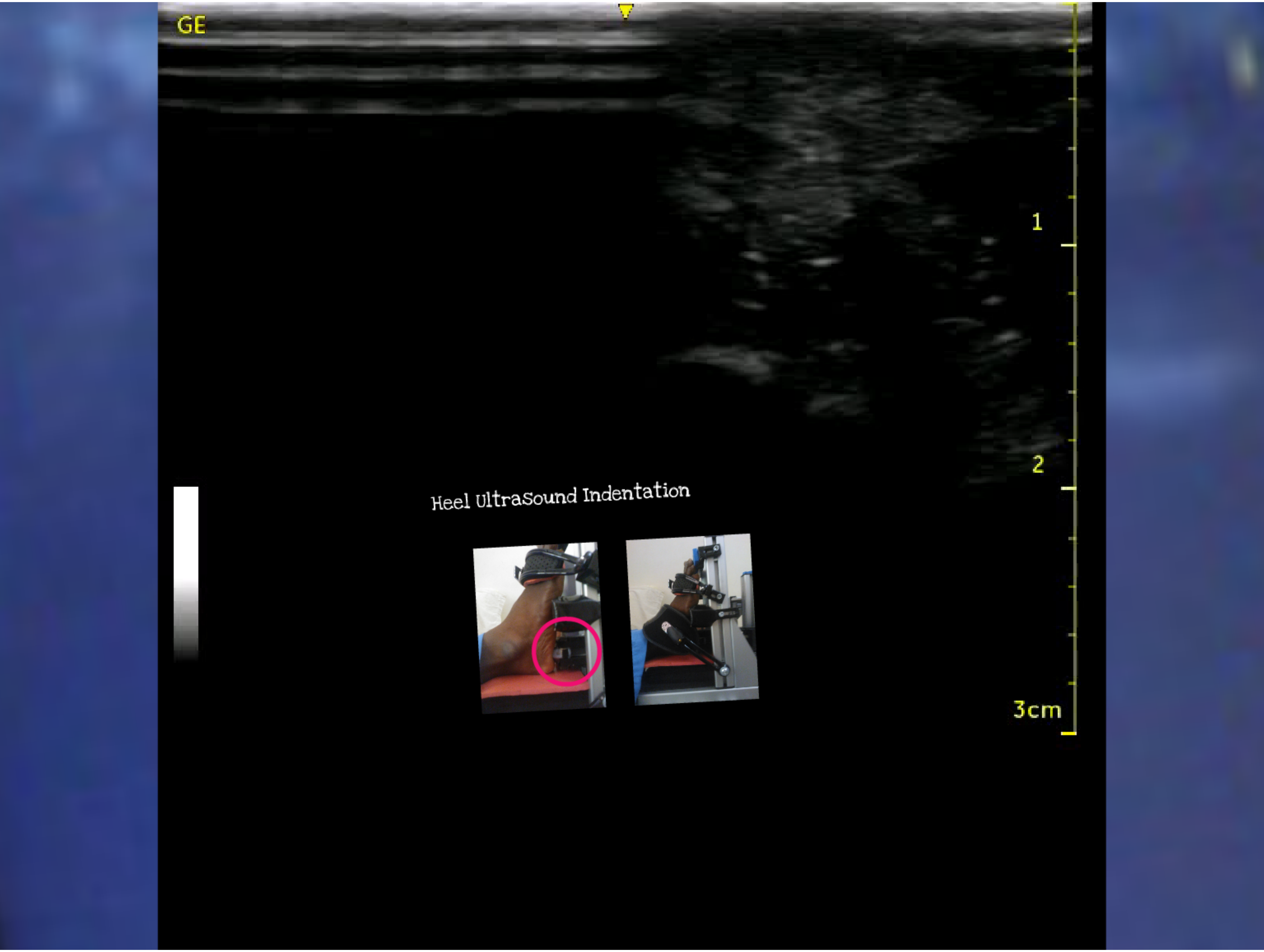
Ultrasound Indentation was performed on 60 individuals (20 Healthy Adults, 20 Adults with Diabetes-without Neuropathy and 20 Adults with Diabetes and Neuropathy).

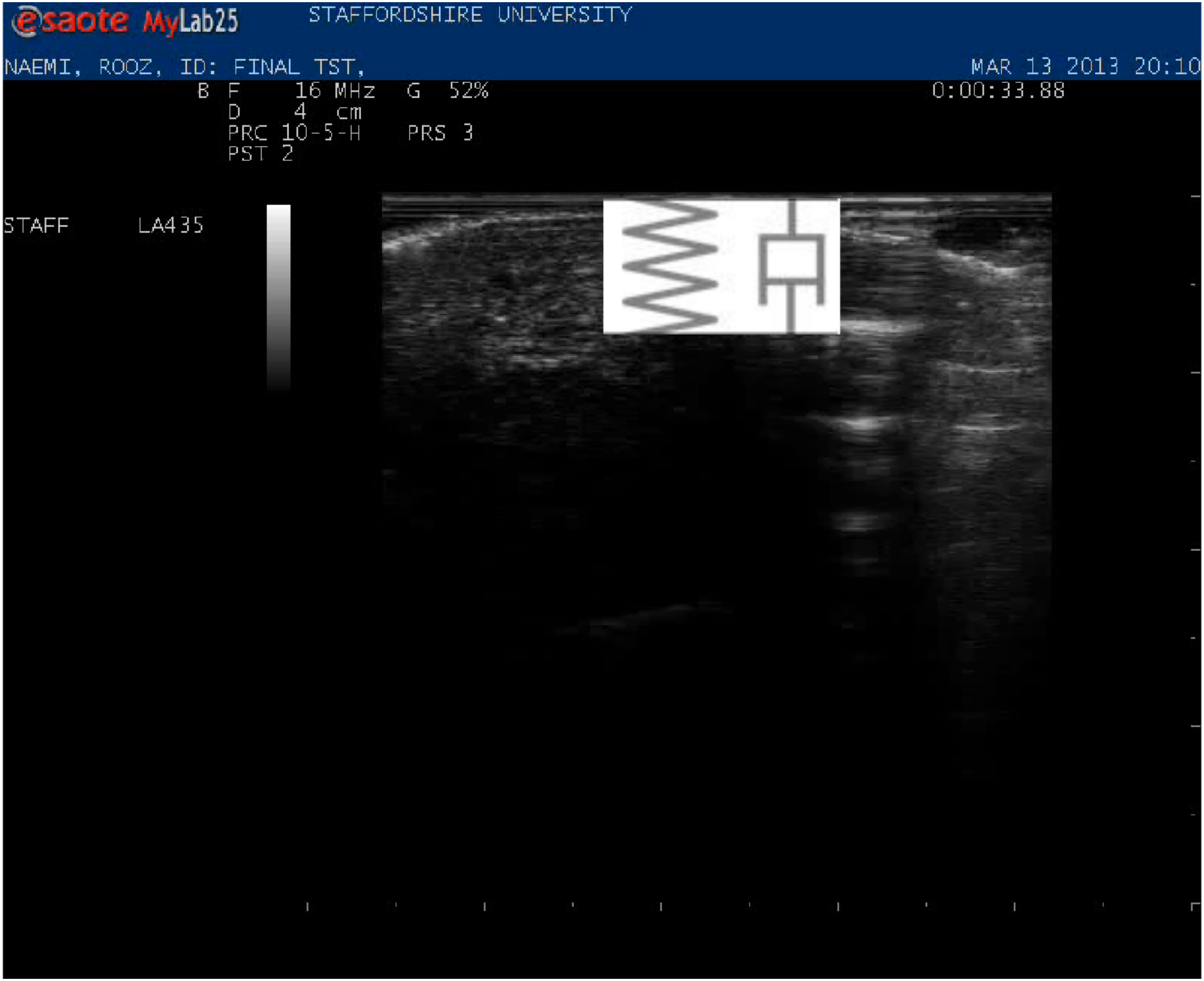
Indentation was performed at two different sites: Heel and first/second Met Head.

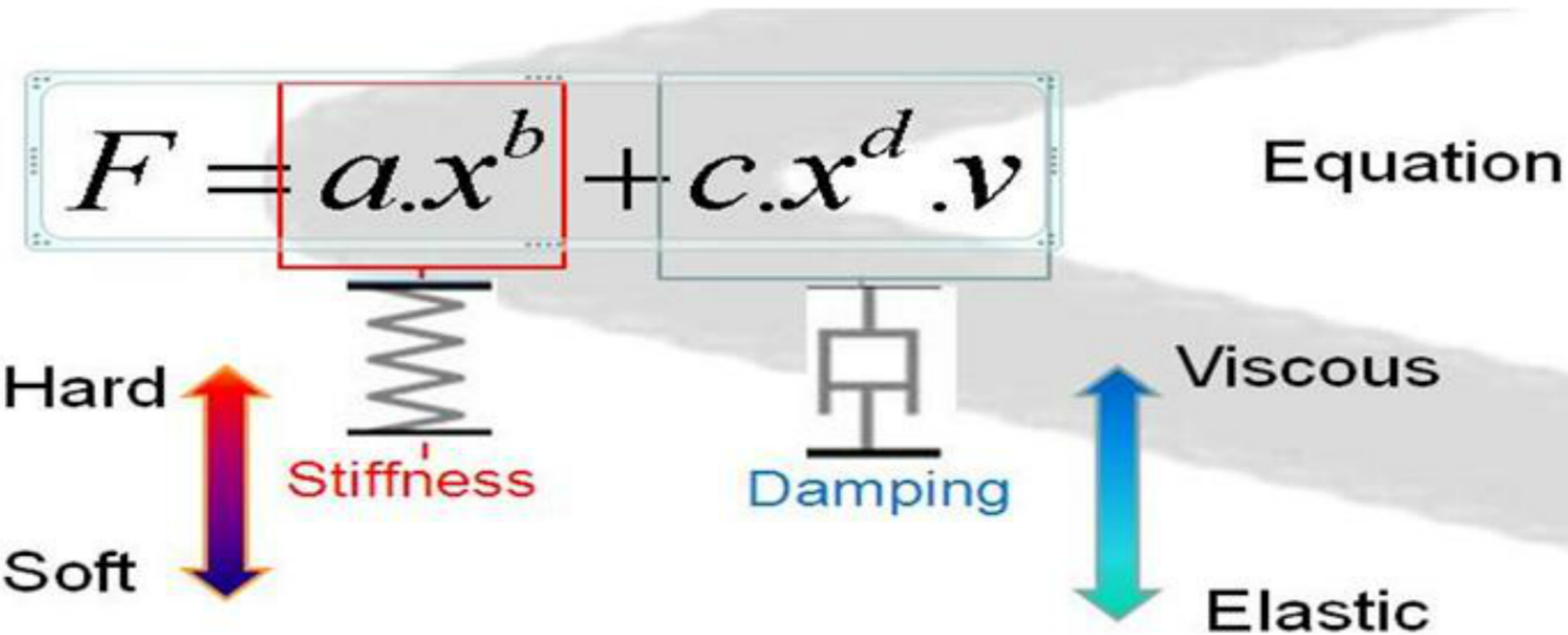
UltraSound Indentation Technique

Ultrasound Indentation was performed on 60 individuals (20 Healthy Adults, 20 Adults with Diabetes-without Neuropathy and 20 Adults with Diabetes and Neuropathy).

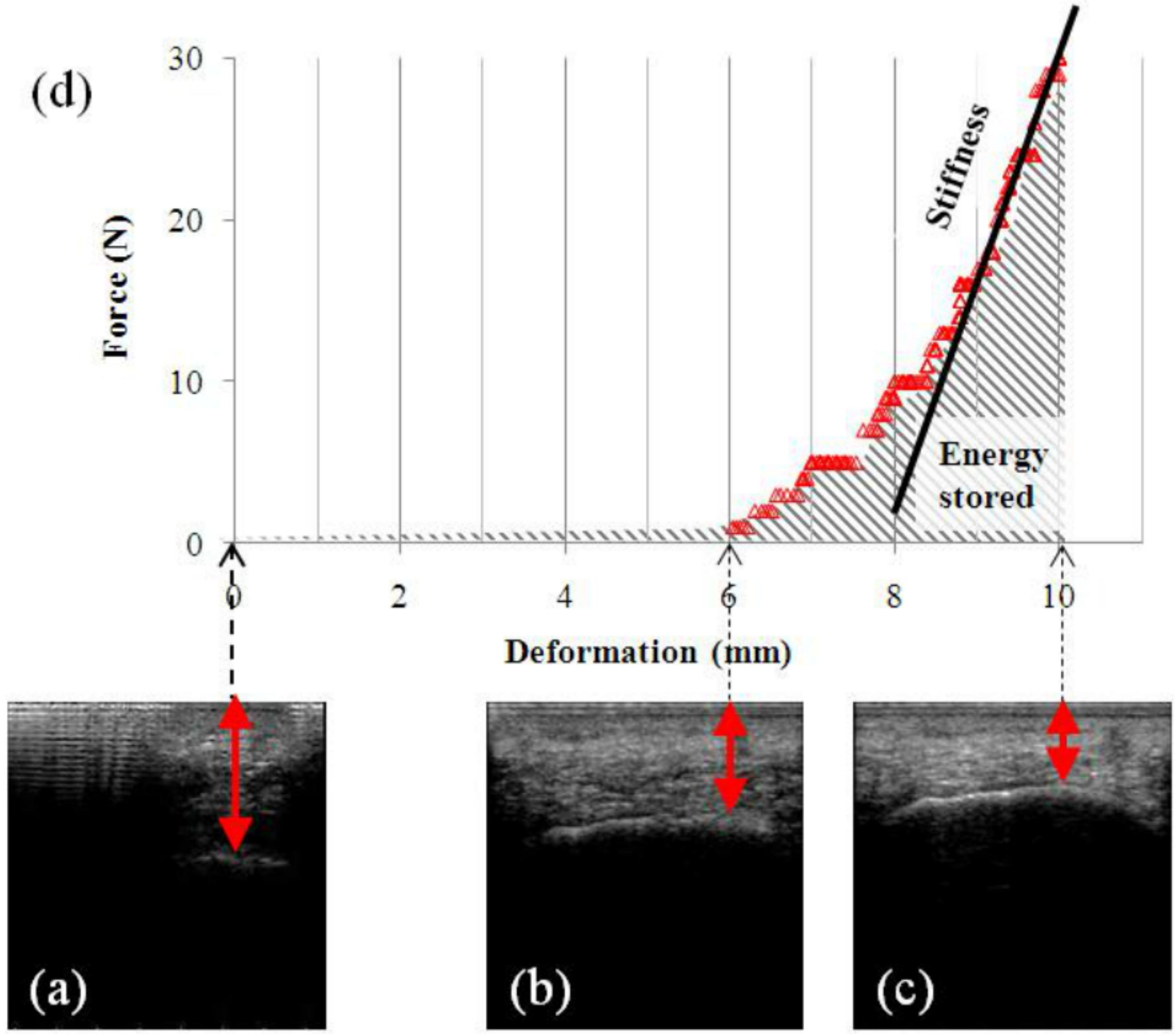
Indentation was performed at two different sites: Heel and first/second Met Head.


GE
1
2
3cm
Heel UltraSound Indentation


esaote MyLab25
STAFFORDSHIRE UNIVERSITY
NAEMI, ROOZ, ID: FINAL TST,
MAR 13 2013 20:10
B F 16 MHz G 52%
D 4 cm
PRC 10-5-H PRS 3
PST 2
0:00:33.88
STAFF LA435



$F = a.x^b + c.x^d.v$
Equation
Hard
Soft
Stiffness
Damping
Viscous
Elastic



2: Representative ultrasound images for the measurement of heel-pad thickness (a) and deformation (a-c) and the results finally recorded after the end of each test (d).

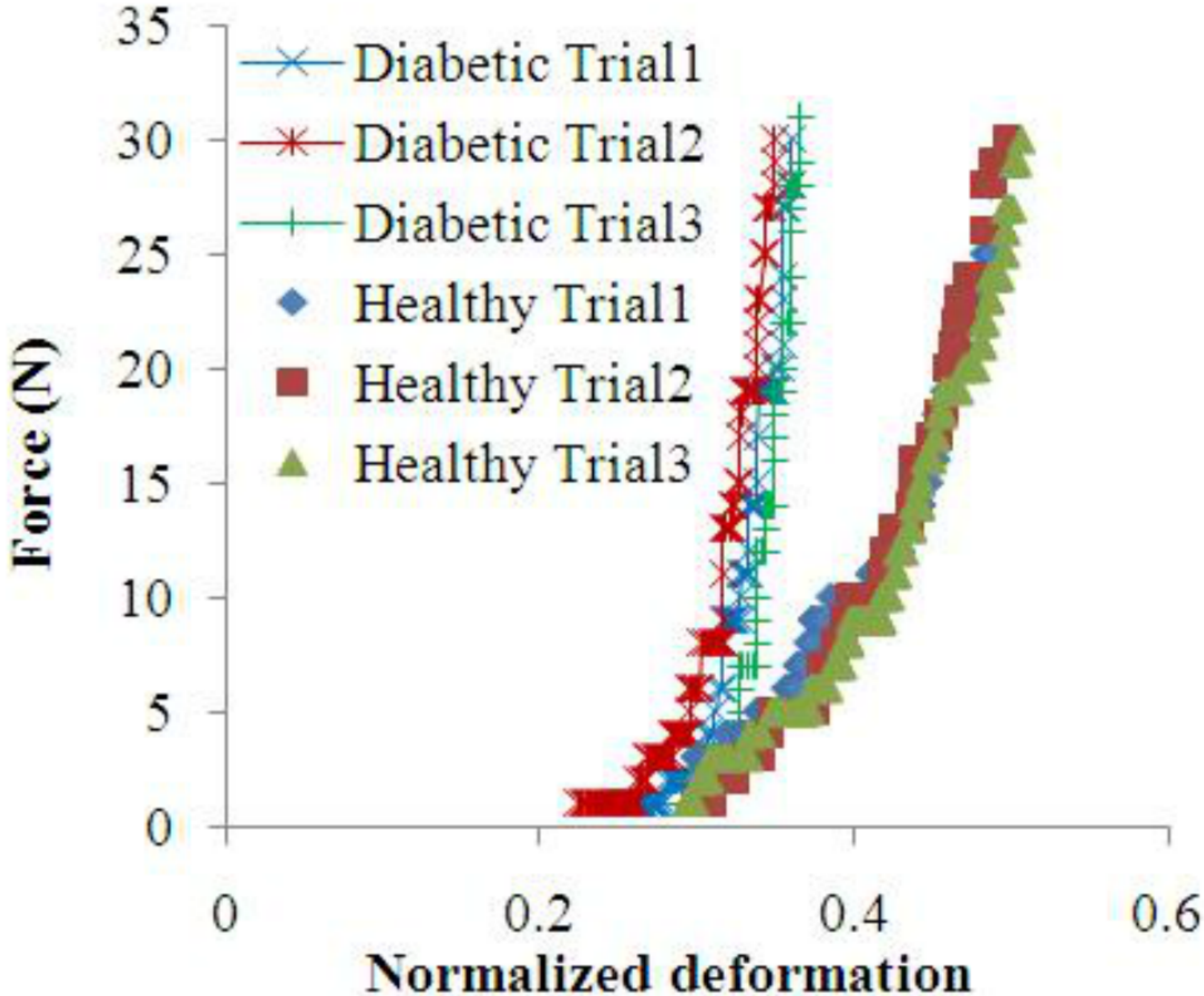


Figure 3: Force deformation data for a healthy and a diabetic volunteer.

Journal of Diabetes and Its Complications 28 (2014) 488–493

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Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

The relationship between the mechanical properties of heel-pad and common clinical measures associated with foot ulcers in patients with diabetes

Panagiotis E. Chatzistergos [a,*], Roozbeh Naemi [a], Lakshmi Sundar [b], Ambadi Ramachandran [b], Nachiappan Chockalingam [a]

[a] CSHER, Faculty of Health Sciences, Staffordshire University, Stoke-on-Trent, United Kingdom
[b] AR Diabetes Hospitals, Chennai, India

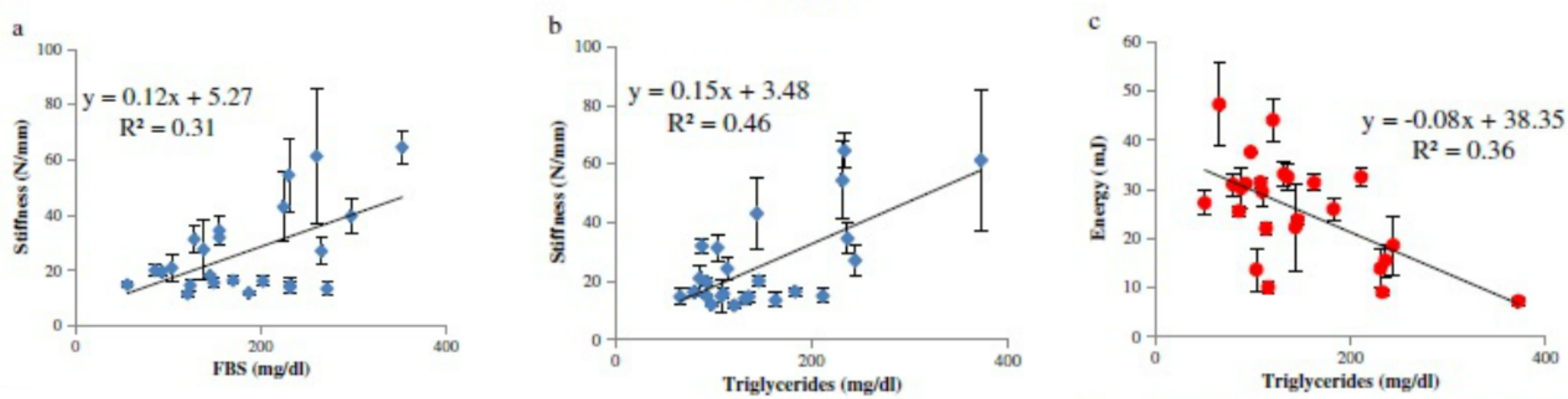


Fig. 4. Scatter-plots for the correlation between Stiffness and FBS (a) Stiffness and Triglycerides (b), and Energy and Triglycerides (c).

Insole material optimization

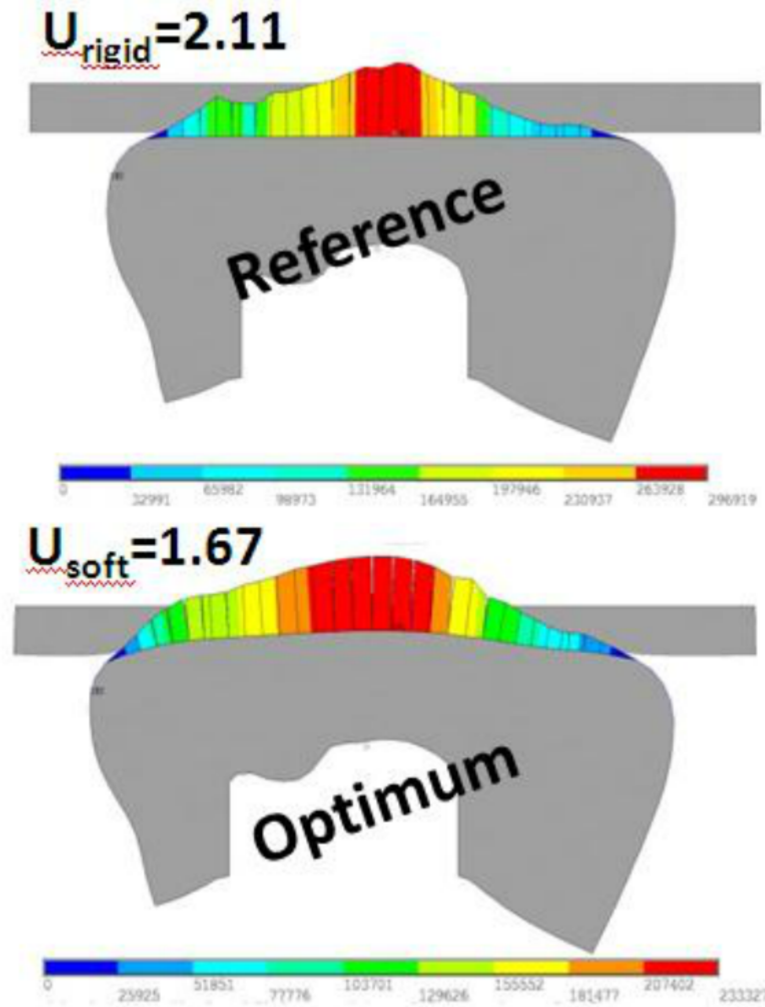
FE modelling

Material coefficients are modified to minimize the difference between maximum and average pressure.

<u>Objective function</u> = 100 * $U^{(N)}_{soft}/U_{rigid}$

<u>Iteration=N</u>

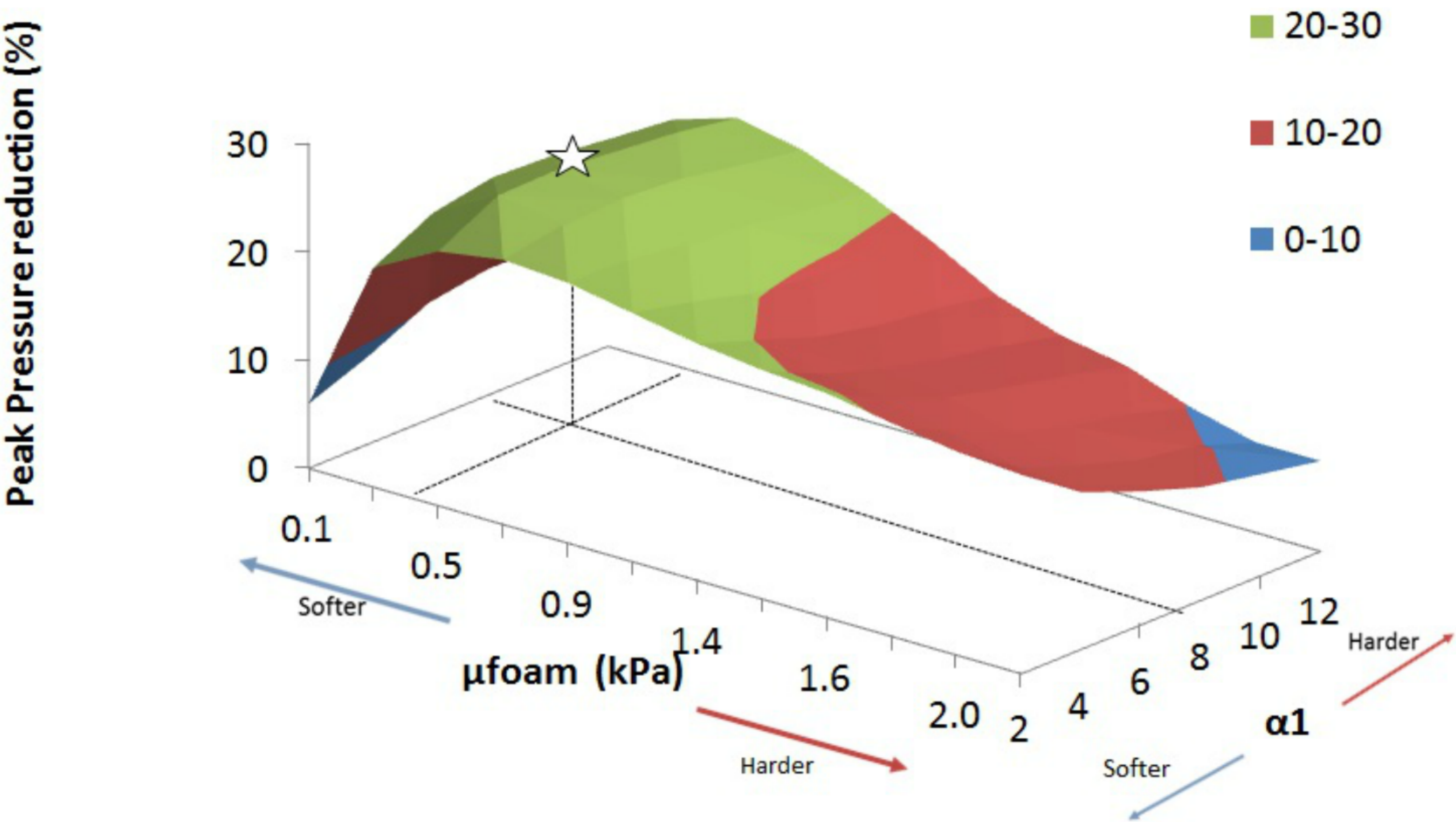
- The FE model is solved for a compliant insole.
- The ratio $U^{(N)}_{soft}=P_{max}/P_{average}$ is calculated.

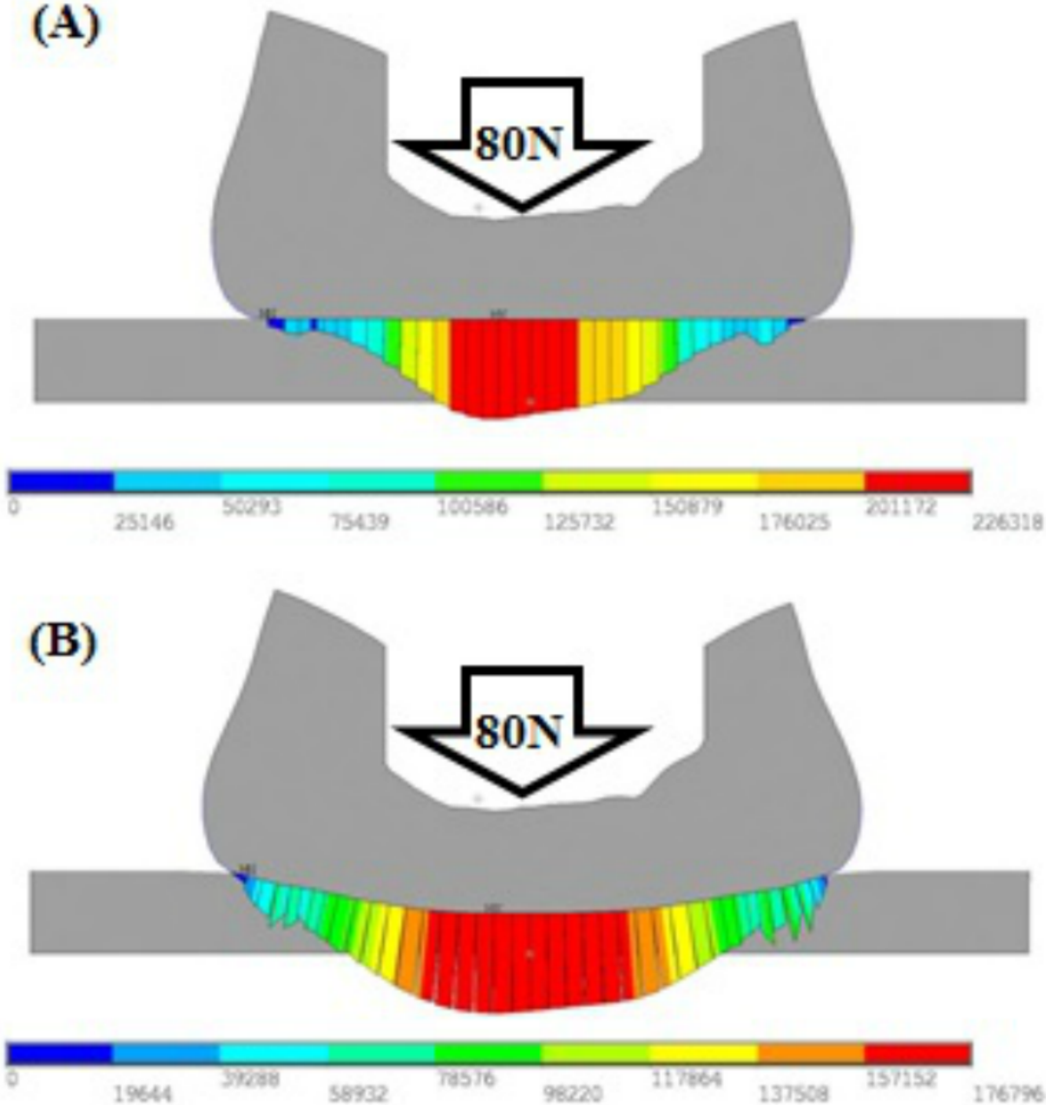


The contact pressure (Pa) between the insole and the soft tissue

Development of a new generation of DIABetic footwear using an integrated approach and SMART materials (DiaBSmart) - *A project funded by the European Commission through Grant Agreement Number 285985 under Industry Academia partnerships and Pathways (FP7-PEOPLE-2011-IAPP)*

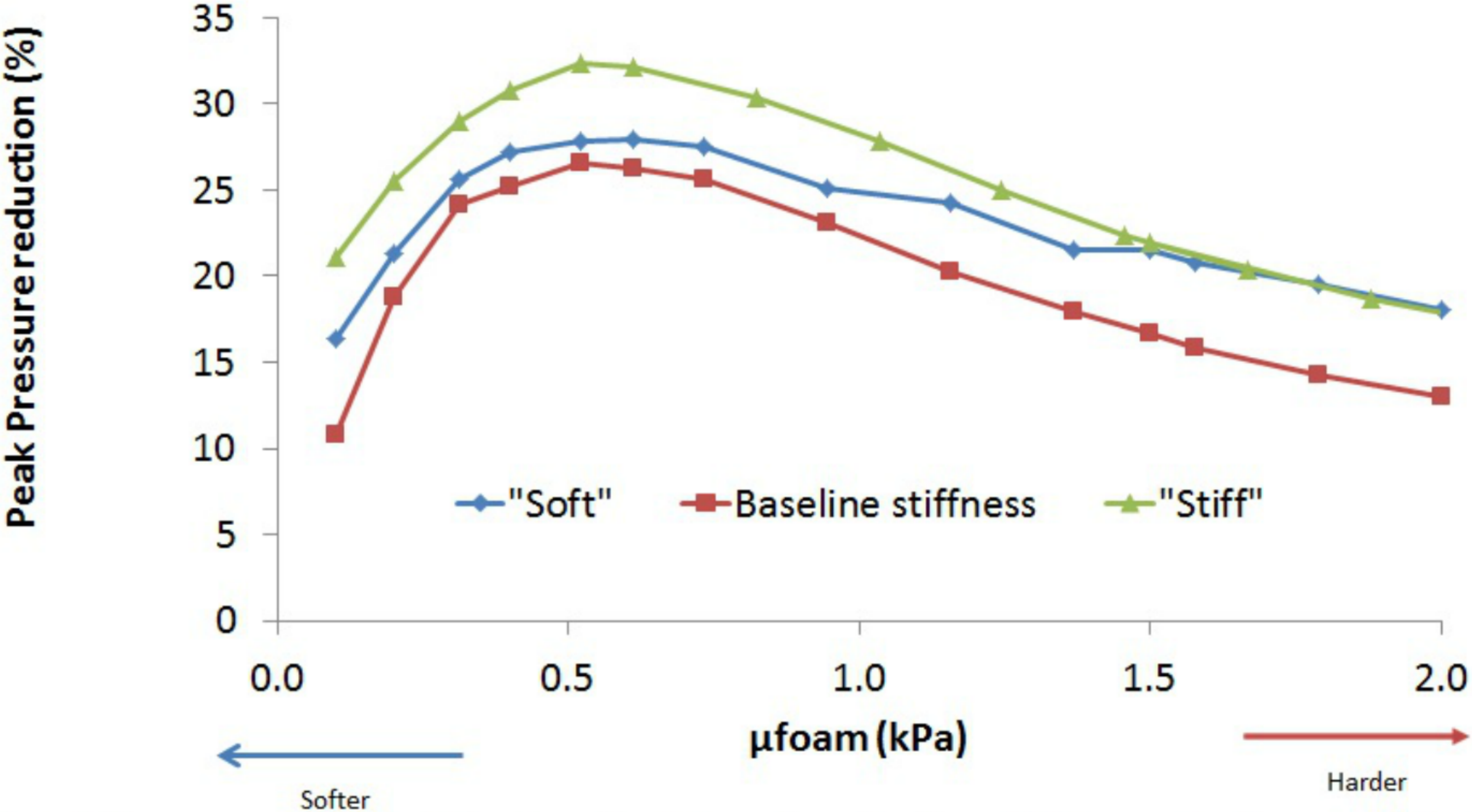
The reduction of peak plantar pressure for different insole stiffness defined by μfoam and αfoam parameters.
The maximum values of each graph are marked with star.





The contact pressure distribution for barefoot standing on a rigid surface (A) or on a 10 mm thick sheet of PU foam (B).

Reduction of peak plantar pressure (%) loading for insoles of different stiffness. The effect of different heel-pad stiffness on the optimum cushioning properties of the foam material.



Insole stiffness was modified by changing the value of μfoam (αfoam =6, vfoam= vPU= 0.06).

Optimum cushioning properties

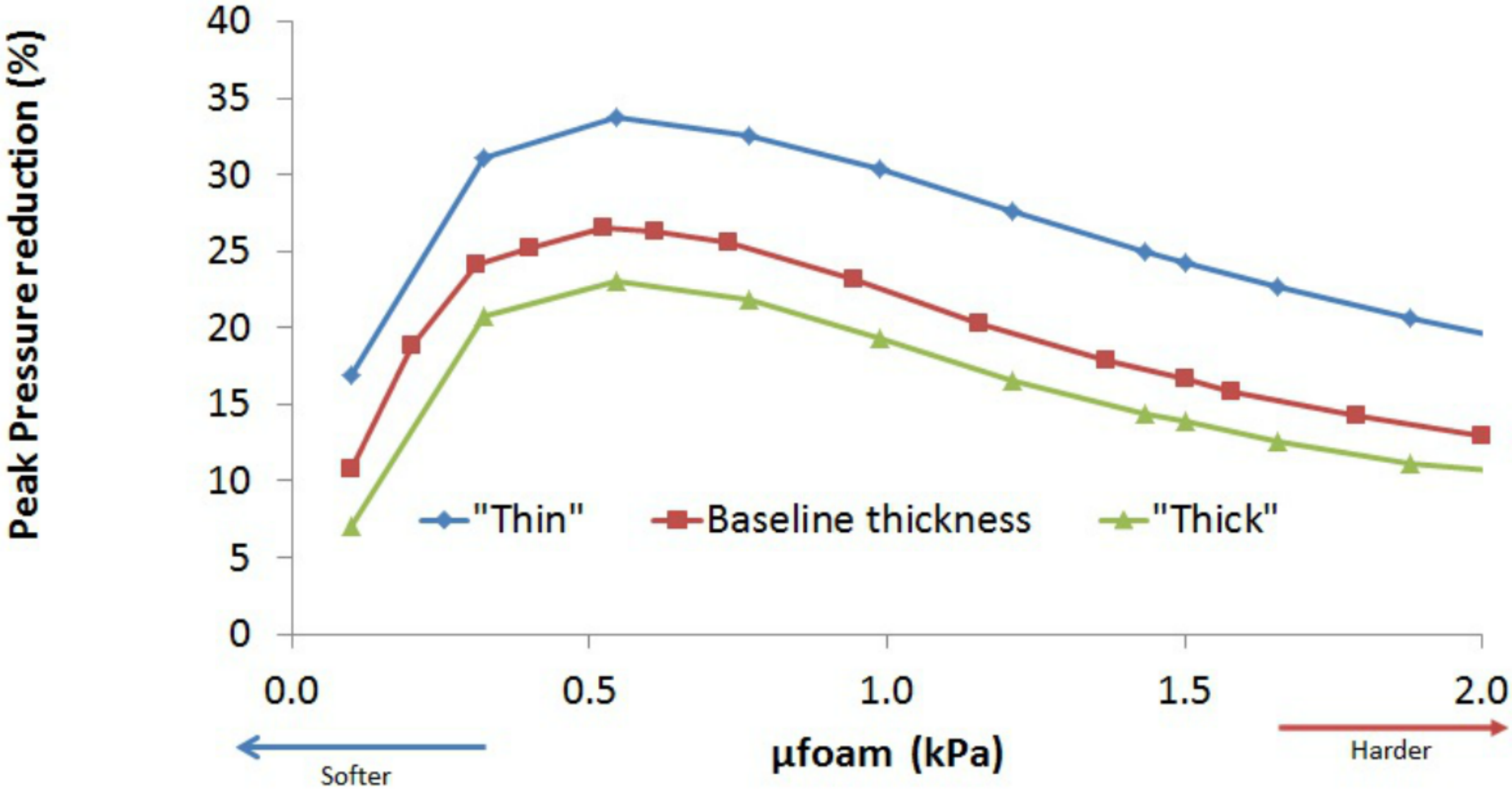
Parametric scenarios: Tissue stiffness

Results:

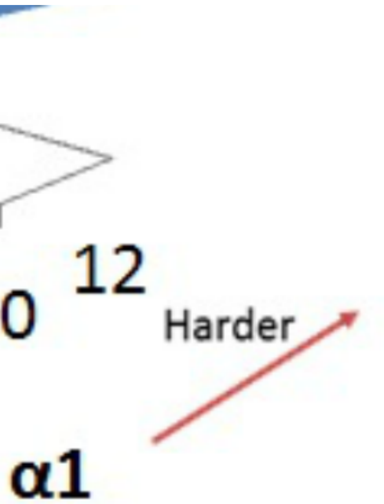
- An optimum insole stiffness exists
- The optimum insole stiffness appears to be the same for all three scenarios.

Conclusion: The “stiffness” of the heel-pad doesn’t influence the “stiffness” of the insole that can achieve the maximum pressure reduction.

Reduction of peak plantar pressure (%) loading for insoles of different stiffness. The effect of different heel-pad thickness on the optimum cushioning properties of the foam material.



Insole stiffness was modified by changing the value of μfoam (αfoam =6, νfoam= νPU= 0.06).



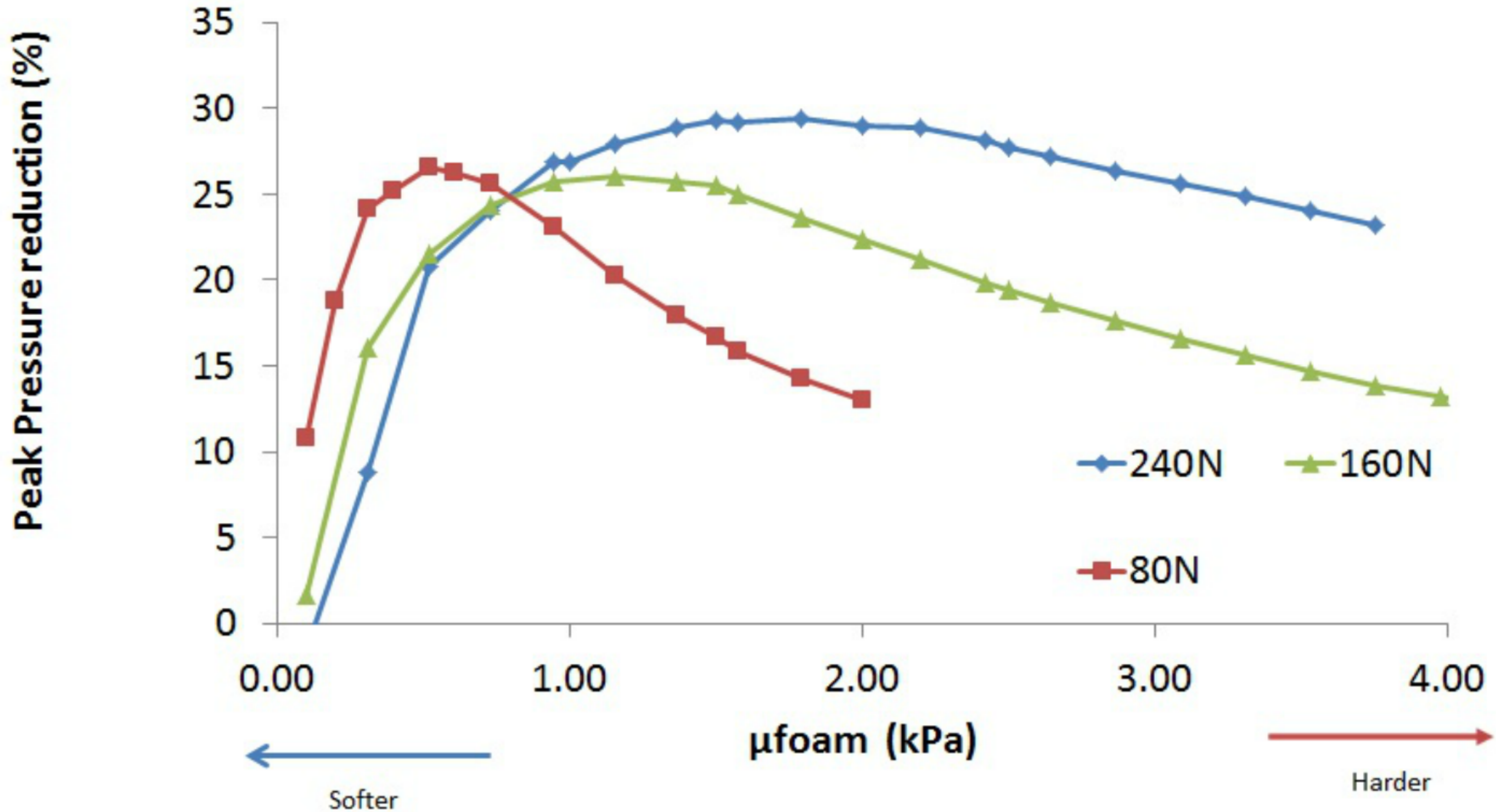
Optimum cushioning properties
Parametric scenarios: Tissue thickness

Results:

- An optimum insole stiffness exists
- The optimum insole stiffness appears to be the same for all three scenarios.

- Conclusion
  - The thickness of the heel pad doesn't influence the stiffness of the insole that can achieve the maximum pressure reduction.

Reduction of peak plantar pressure (%) loading for insoles of different stiffness. The effect of different loading on the optimum cushioning properties of the foam material.



Insole stiffness was modified by changing the value of µfoam (αfoam =6, vfoam= vPU= 0.06).

Optimum cushioning properties
Parametric scenarios: Loading Magnitude

Results:

- The insole stiffness that achieves maximum pressure reduction is different for three loading scenarios.
- Their stiffness difference is 45%.

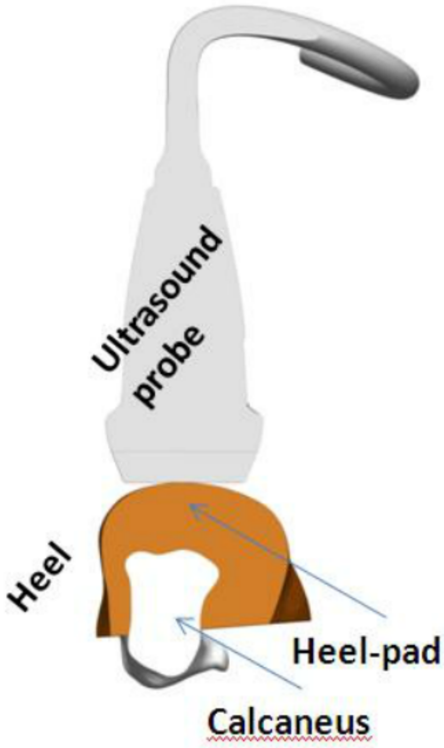
- Conclusion
  - To maximize plantar pressure reduction for people that apply lower load to their feet, softer insoles are needed.

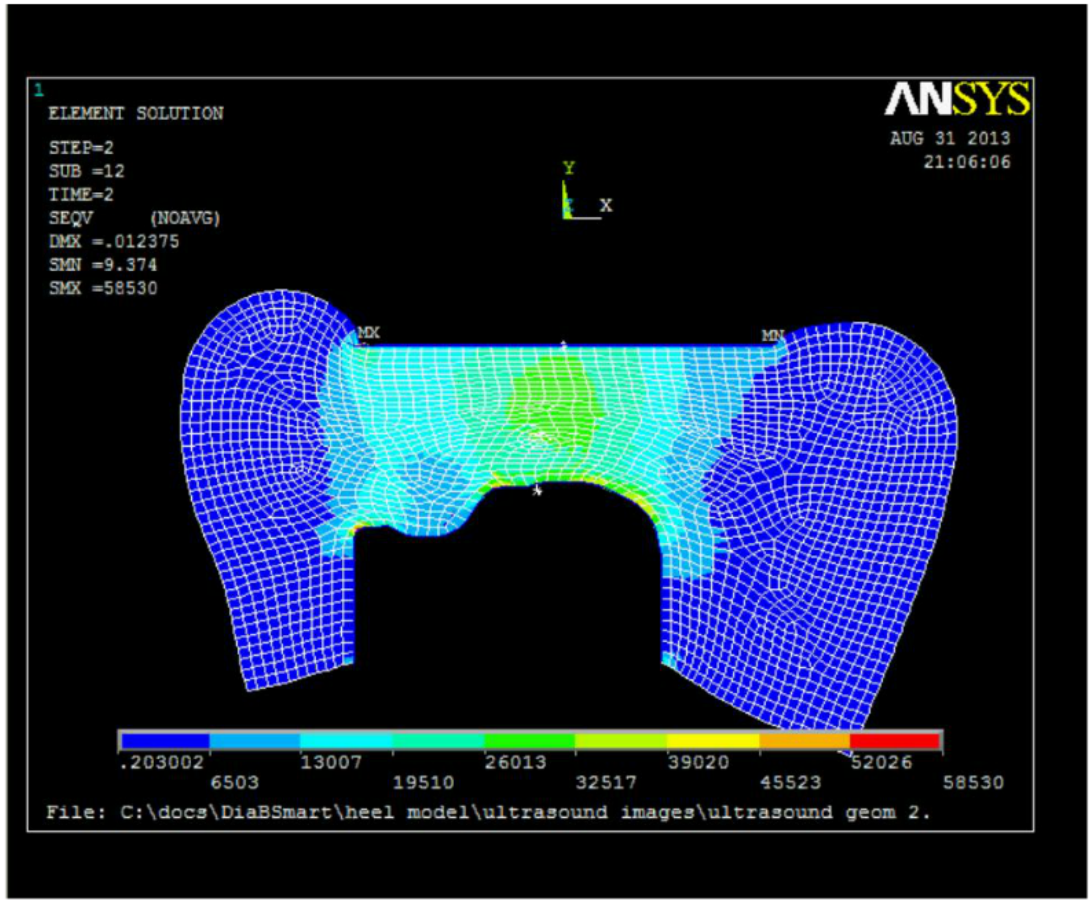
Conclusion

The results indicated that although heel-pad stiffness and thickness influence plantar pressure but they do not influence the optimum insole properties.

On the other hand loading appears to significantly influence the optimum insole material properties.

These results indicate that parameters that affect the loading of the plantar soft tissues such as a person's body mass or foot loading during stance phase should be carefully considered for insole material selection.



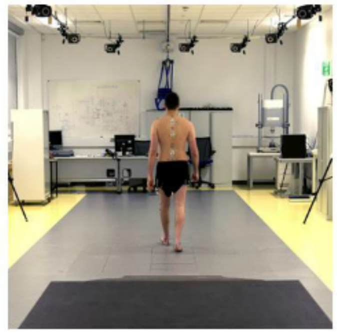


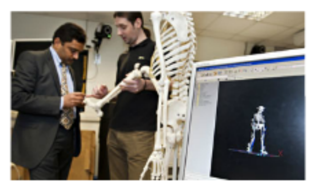
Work is in progress to determine the effect of insole mechanical properties on the internal stress/strain of plantar soft tissue.

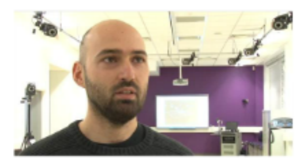
The proposed approach upon validation can have implications in diagnosis and prescription aspects of Diabetic foot and footwear and can have significant impact on reducing Diabetic foot ulceration risk.

DiaBSmart is funded by the European Commission through Grant Agreement Number 285985 under Industry Academia partnerships and Pathways (FP7-PEOPLE-2011-IAPP)

This project led by Staffordshire University is funded by the European Commission through Grant Agreement Number 285985 under Industry Academia partnerships and Pathways (FP7-PEOPLE-2011-IAPP)







Thanks!