

La **S**indrome del **piede diabetico**: competenze in azione con uno sguardo al futuro



**Le ortesi nella prevenzione primaria
e nella prevenzione delle recidive e
l'importanza del collaudo**

*Dr.ssa Cristiana Vermigli
Ingegnere Moreno D'Amico*

La **S**indrome del **piede diabetico**: competenze in azione con uno sguardo al futuro



Le calzature



Practical guidelines on the prevention and management of diabetes-related foot disease

IWGDF 2023 update



Part of the 2023 IWGDF Guidelines on
the prevention and management of
diabetes-related foot disease



Guidelines on the prevention of foot ulcers in persons with diabetes

IWGDF 2023 update



Part of the 2023 IWGDF Guidelines on
the prevention and management of
diabetes-related foot disease





3.4 ENCOURAGE ROUTINE WEARING OF APPROPRIATE FOOTWEAR

In persons with diabetes and IWGDF risk category 1 or higher, wearing inappropriate footwear or walking barefoot are major causes of foot trauma leading to foot ulceration. Persons with LOPS must have (and may need financial assistance to acquire) appropriate footwear, and should be encouraged to wear this at all times, both indoors and outdoors. All footwear should be adapted to conform to any alteration in foot structure or foot biomechanics affecting the person's foot.

For footwear to be considered appropriate, the inside length of the shoe should be 1-2 cm longer than the foot and should not be either too tight or too loose (see Figure 3). The internal width should equal the width of the foot at the metatarsal phalangeal joints (or the widest part of the foot), and the height should allow enough room for all the toes. Evaluate the fit with the patient in the standing position, preferably later in the day (when they may have foot swelling). If there is no off-the-shelf footwear that can accommodate the foot (e.g., if the fit is poor due to foot deformity) or if there are signs of abnormal loading of the foot (e.g., hyperaemia, callus, (previous) ulceration), prescribe therapeutic footwear, possibly including extra-depth shoes, custom-made footwear and custom-made insoles. This may also include the prescription and fabrication of (toe) orthoses.

Figure 3: Footwear should be sufficiently wide to accommodate the foot without excessive pressure on the skin



For people who have healed from a plantar foot ulcer, ensure that the therapeutic footwear has a demonstrated plantar pressure relieving effect during walking. When possible, demonstrate this plantar pressure relieving effect with appropriate equipment, as described in the prevention guidelines (1). Instruct the person to never again wear the same shoe that has caused an ulcer. Take protective measures to prevent heel ulceration in (temporarily) bedridden patients (either at home or admitted to an institution).

For people who have healed from a plantar foot ulcer, ensure that the therapeutic footwear has a demonstrated plantar pressure relieving effect during walking. When possible, demonstrate this plantar pressure relieving effect with appropriate equipment, as described in the prevention guidelines (1). Instruct the person to never again wear the same shoe that has caused an ulcer. Take protective measures to prevent heel ulceration in (temporarily) bedridden patients (either at home or admitted to an institution).

VERIFICA CALZATURE E PLANTARI







68-704-89

38+



IWGDF Prevention Guideline



1. In a person with diabetes who is at risk of foot ulceration
 - a. and with no or limited foot deformity, no pre-ulcerative lesions and no plantar ulcer history (IWGDF risk 1-3), educate to wear footwear that accommodates the shape of the feet and that fits properly. (Strong; Low)
2. and with a foot deformity that significantly increases pressure or a pre-ulcerative lesion (IWGDF risk 2 or 3), consider prescribing extra-depth shoes, custom-made footwear, custom-made insoles, and/or toe orthoses. (Strong; Low)
3. and with a healed plantar foot ulcer (IWGDF risk 3), prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking, to help prevent a recurrent plantar foot ulcer; furthermore, encourage the person to consistently wear this prescribed footwear, both indoors and outdoors. (Strong; Moderate)

Manufactured Shoes in the Prevention of Diabetic Foot Ulcers

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GIOVANNA MONTICONE, MD
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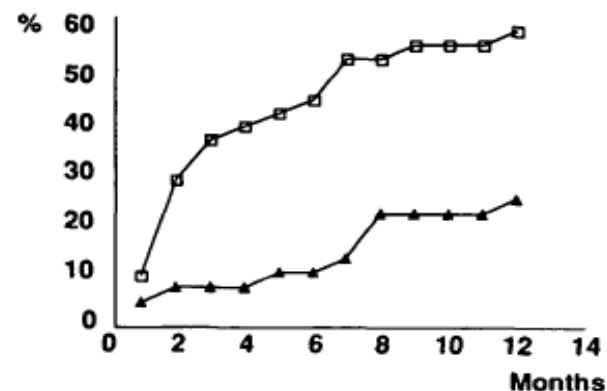


Figure 1—Cumulative incidence of foot ulcer relapses in control (□) and Podiabetes (▲) groups during 12 months of observation.

% recidiva ulcere

- 58.3% gruppo con calzature non terapeutiche
- 27.7% gruppo con calzatura terapeutica

Table 1—Characteristics of the patients

	n	M/F	Age (years)	Duration (years)	Type I/II
Podiabetes	33	20/13	59.6 ± 11	16.8 ± 12.7	8/25
Control	36	23/13	60.2 ± 8.2	17.5 ± 8	9/27

GRATIS DIABETIC THERAPEUTIC FOOTWEAR PRESENTING RESEARCH MATTHEW L. MACIEJEWSKI

Diabetes care, 2004



Uccioli Study Shoe Worn By Men and Women (20)



Chantelau Study Shoe Worn By Women (21)



Reiber Study Shoe Worn By Women (24)

I dati sull' efficacia delle calzature nei pazienti diabetici sono ancora pochi e sono necessari ulteriori studi prospettici randomizzati caso/controllo, al fine di identificare per ciascuna condizione clinica la miglior opzione terapeutici

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

The International Journal of Lower
Extremity Wounds
11(1) 59–64
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DOI: 10.1177/1534734612438729
<http://ijlew.sagepub.com>
SAGE

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Gruppo A: trattamento standard
(educazione e calzature confortevoli)

Gruppo B: educazione e calzature ortopediche
con ortesi plantare

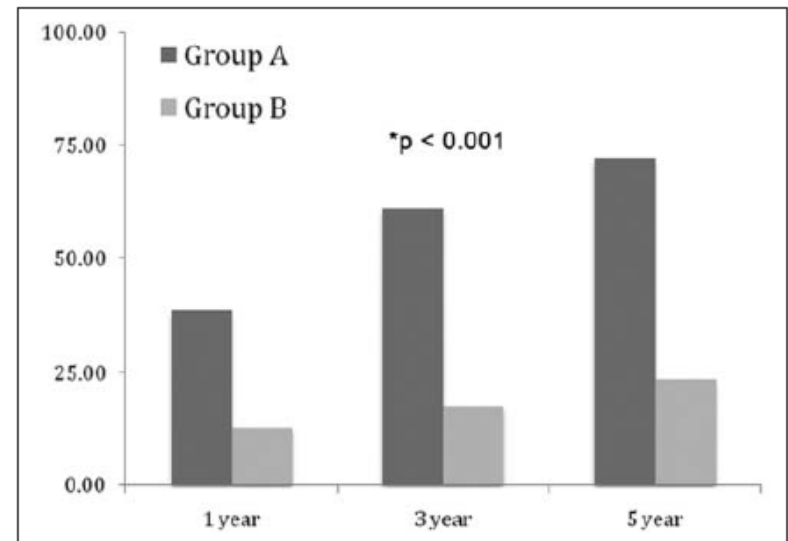


Figure 1. Cumulative incidence of ulcers and recurrences in both groups after 1, 3, and 5 years of follow-up



AMPIA E COMODA ALLACCIATURA
SUL DORSO DEL PIEDE

FODERA ASSORBENTE ANTIBATTERICA
TRASPIRANTE - ANTIODORE

TOMAIA
SENZA CUCITURE

FORTE POSTERIORE
DELLA TOMAIA
RINFORZATO

SCAFO SUOLA IN P.U.
Morbidezza 48/52 Shore

SUOLA
BICOMPONENTE

BARRA DI SVOLGIMENTO
ANTERIORE DELLA SUOLA

PROFILO SMUSSATO
POSTERIORE DEL TACCO

BATTISTRADA IN T.P.U. AD ALTA
RESISTENZA ALL'ABRASIONE
Morbidezza 63/67 Shore



Therapeutic Footwear for the Neuropathic Foot

An algorithm

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Neuropathy may bring about changes in form and function of the foot, which may lead to ulceration and progressive deformity. These manifestations often require specially adapted footwear. A comprehensive concept of the medical, functional, and technical requirements for this type of footwear is still lacking to date. In this article, we present an algorithm that should facilitate prescription and manufacture of adequate shoes. This algorithm attempts to establish a link between the requirements from a medical and functional point of view and the technical possibilities of orthopedic shoe technology.

ferent features of a neuropathic foot. Because neuropathy commonly occurs in diabetes, we will also mention one of its consequences, limited joint mobility, which is not directly related to neuropathy (18).

1. Sensory dysfunction

1.1. Loss of sensory function

In the long term, reduction of sensory function may lead to complete loss of sensation in the foot. We speak of loss of

Therapeutic Footwear for the Neuropathic Foot

An algorithm

Clinical Features	Orthosis	Shoe Height	Pivot Point	Sole
Loss of protective sensation	Yes	<i>Low</i>	<i>N.A.</i>	
L.J.M.	Yes	<i>Low</i>		<i>Rigid</i>
Pes cavus /Hammer toes	Yes	<i>Bottine</i>	<i>Proximal</i>	<i>Rigid</i>
Flat foot /Allux valgus	Yes	<i>Bottine</i>		<i>Rigid</i>
Previous ulcer/amputations	Yes	<i>High</i>	<i>Proximal</i>	<i>Rigid</i>
Chronic Charcot	Yes	<i>High</i>	<i>Proximal</i>	<i>Rigid</i>

[Dahmen et al .Diabetes Care 2001]

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I Plantari

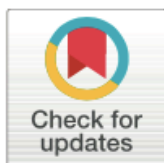
RESEARCH ARTICLE

Data-driven CAD-CAM vs traditional total contact custom insoles: A novel quantitative-statistical framework for the evaluation of insoles offloading performance in diabetic foot

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C. Vermigli⁵**

Aims:

- 1) To develop a novel quantitative-statistical framework (QSF) for the evaluation and design of the insoles' offloading performance through in-shoe pressure measurement;
- 2) To compare the pressure-relieving efficiency of
 - traditional shape- based total contact customised insoles (TCCI)
 - CAD-CAM approach by the QSF.

We recruited **30** neuropathic diabetic patients
in cross-sectional study design



from a pool of
220 patients screened in
the Diabetic Foot Centre
at the Department of Endocrinology and Metabolism of Perugia University

Classificazione del Rischio di Ulcere ai piedi nel Diabete

Classe	Caratteristiche	Rischio	Controlli
1	Assenza di neuropatia sensitiva	Assente	annuali
2	Presenza di neuropatia sensitiva	Medio	6 mesi
3	Presenza di neuropatia sensitiva, segni di vasculopatia periferica e/o deformità dei piedi	Alto	3 mesi
4	Pregressa ulcera	Altissimo	1-3 mesi

(International Working Group on the Diabetic Foot, 2010)

CENTRO REGIONALE SPECIALISTICO PIEDE DIABETICO

(DEL. REG. n 458 del 08-04-1999)

SCHEDA RACCOLTA DATI

DATI ANAGRAFICI DEL PAZIENTE	
CODICE PAZIENTE: _	
DATA DI NASCITA _/ _/ _	Tel: _____
Sesso M F	

Anamnesi patologica Remota del Piede

Ulcera Pgressa	SI ☐ NO ☐ SX ☐ DX ☐
Durata	Sede
Amputazione Pgressa	SI ☐ NO ☐ SX ☐ DX ☐
Causa	
Osteoartropatia di Charcot	SI ☐ NO ☐ SX ☐ DX ☐
Sede	

Esame Obiettivo

Deformità digitali	SI□NO□	SX□DX□
Sede		
Prominenze ossee	SI□NO□	SX□DX□
Sede		
Osteoartropatia di Charcot	SI□NO□	SX□DX□
Sede		
Ipercheratosi	SI□NO□	SX□DX□
Sede		
Atrofia muscoli interossei	SI□NO□	SX□DX□
Alterazioni ungueali	SI□NO□	SX□DX□
Sede		
Flittene	SI□NO□	SX□DX□
Sede		
Fissurazioni	SI□NO□	SX□DX□
Sede		
Escoriazioni superficiali	SI□NO□	SX□DX□
Sede		
Micosi interdigitali	SI□NO□	SX□DX□
Sede		
Piccoli ematomi	SI□NO□	SX□DX□
Sede		
Ulcera in atto	SI□NO□	SX□DX□
Sede		

Vasculopatia Periferica

Polsi	SX	DX
Popliteo	presente ☐ ipo ☐ assente ☐	presente ☐ ipo ☐ assente ☐
Tibiale Posteriore	presente ☐ ipo ☐ assente ☐	presente ☐ ipo ☐ assente ☐
Pedidio	presente ☐ ipo ☐ assente ☐	presente ☐ ipo ☐ assente ☐

ABI SX _____ DX _____

(spec 100%; sens 95% se non neuropatia; Faglia, 1999)

Neuropatia Periferica

Sensibilità Vibratoria (volts)		Monofilamento
	SX DX	Piede SX Normale ☐ Ridotto ☐ Assente ☐
Malleolo	_____	Piede DX Normale ☐ Ridotto ☐ Assente ☐
Alluce	_____	

(sens 100%; spec 77% ;Armstrong, 1998)

DNI

1) Ispezione dei piedi

	SI (0)	NO (1)
--	-----------	-----------

Destro : Normale ? _____

Se NO, valuta le seguenti alterazioni

_____	Deformità
_____	Cute secca
_____	Infezione
_____	Ulcera (1)

SI (0)	NO (1)
-----------	-----------

Sinistro : Normale ? _____

Se NO, valuta le seguenti alterazioni

_____	Deformità
_____	Cute secca
_____	Infezione
_____	Ulcera (1)

Presente (0)	Presente con rinforzo (0,5)	Assente (1)
-----------------	--------------------------------	----------------

2) Riflessi achillei

Destro	_____	_____	_____
Sinistro	_____	_____	_____

Presente (0)	Presente con rinforzo (0,5)	Assente (1)
-----------------	--------------------------------	----------------

3) Sensibilità vibratoria all'alluce

Destro	_____	_____	_____
Sinistro	_____	_____	_____

TOTALE _____ / 8 Punti

Table 1. Risk related characteristics of the participants.

Participant Characteristics	Values/Percentages	
N. Patients	30	
HbA1c	7.40±0.87	
History of Foot Ulcer	26.6% (8/30)	
Risk Class 1	60.0% (18/30)	
Risk Class 2	10.0% (3/30)	
Risk Class 3	30.0% (9/30)	
Ankle-Brachial Pressure Index	Right 1.13±0.2	Left 1,14±0.2
Foot deformities	53.3% (16/30)	
Bony prominence	46.6% (14/30)	
Limited Joint Mobility	16.6% (5/30)	
Hyperkeratosis	100% (30/30)	
Foot small muscle atrophy	20.0% (6/30)	
Onychodystrophy	66.6% (20/30)	
Previous use of Foot Orthoses	56.6% (17/30)	

Classe 3 21

Classe 4 9

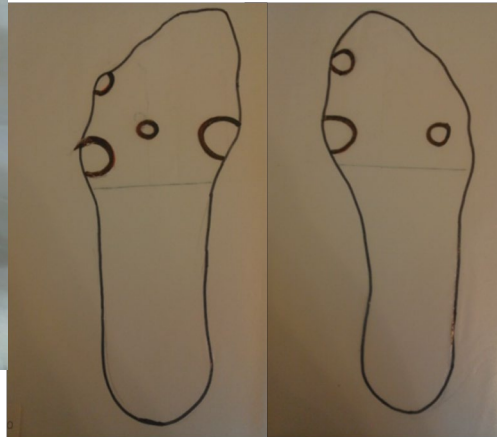
TEST EXECUTION AT T1 VISIT

In the first session, the subjects were provided with special sandals with a neutral flat insole (NFI)



TEST EXECUTION AT T1 VISIT

- Hyperkeratosis and previous ulcer were detected with picture and blueprints



TEST EXECUTION AT T1 VISIT

- 1-Entering patient data
- 2-Choice of footwear and insole
- 3-Application of the Pedar (Novel Gmbh) multi-sensor slab system
- 4-Preparation of sensorized insoles
- 5-Static test execution
- 6-Test execution in dynamics
- 7-Removal of the multi-sensor insole system Pedar (Novel Gmbh)
- 8-Impression taking
- 9-Macroscopic processing of baropodometric analysis data

TEST EXECUTION AT T1 VISIT

- 1-Entering patient data

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Start a New Session Change Subject File Name: PGPTGCS00 Previous Sessions:
A: 09-JUN-2014
B: 06-AUG-2014

Anagraphic Data
Surname: 17PGPD001 Search
Name: TG
Birth Date: 07 - NOV - 1964 Confirm
Day Month Year Undo
Pathology: PIEDE DIABETICO

Nome da inserire nell'interfaccia Pedar:
(Fare Copia e Incolla)
17PGPD001 TG
☐ Pedar Export Mode

Acquisition Type
☒ Standing ☐ Anteversion
☐ Right Bending ☐ Retroversion
☐ Left Bending ☐ Self-Correction
☐ Gait ☐ Postural Sway
☐ Wedged ☐ Forward Bending

Acquisition Flow
Acquire

Pedar-X status Check Pedar State
Data collection can't be started

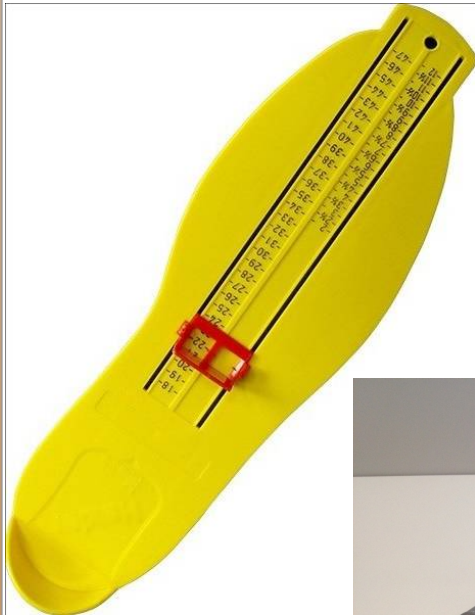
Acquisition Setup
☒ Fixed Time Duration (s): 10 Free Time
☐ Underfoot Wedge Wedge Setup
Wedge Size (mm): 0 Rt Lf
Shoes Type: SANDALO ELECTRA 3 Edit Shoe Codes

Ausili Tecnici
AT #1 Edit AT #1
AT #2 Edit AT #2

Comment Code: PROVA SUOLETTA PEDAR Edit Comment
Weight (Kg): 82 Height (cm): 177
Launch BIG
☐ Attiva Metronomo Metronomo: 0.65

TEST EXECUTION AT T1 VISIT

2-Choice of footwear and insole



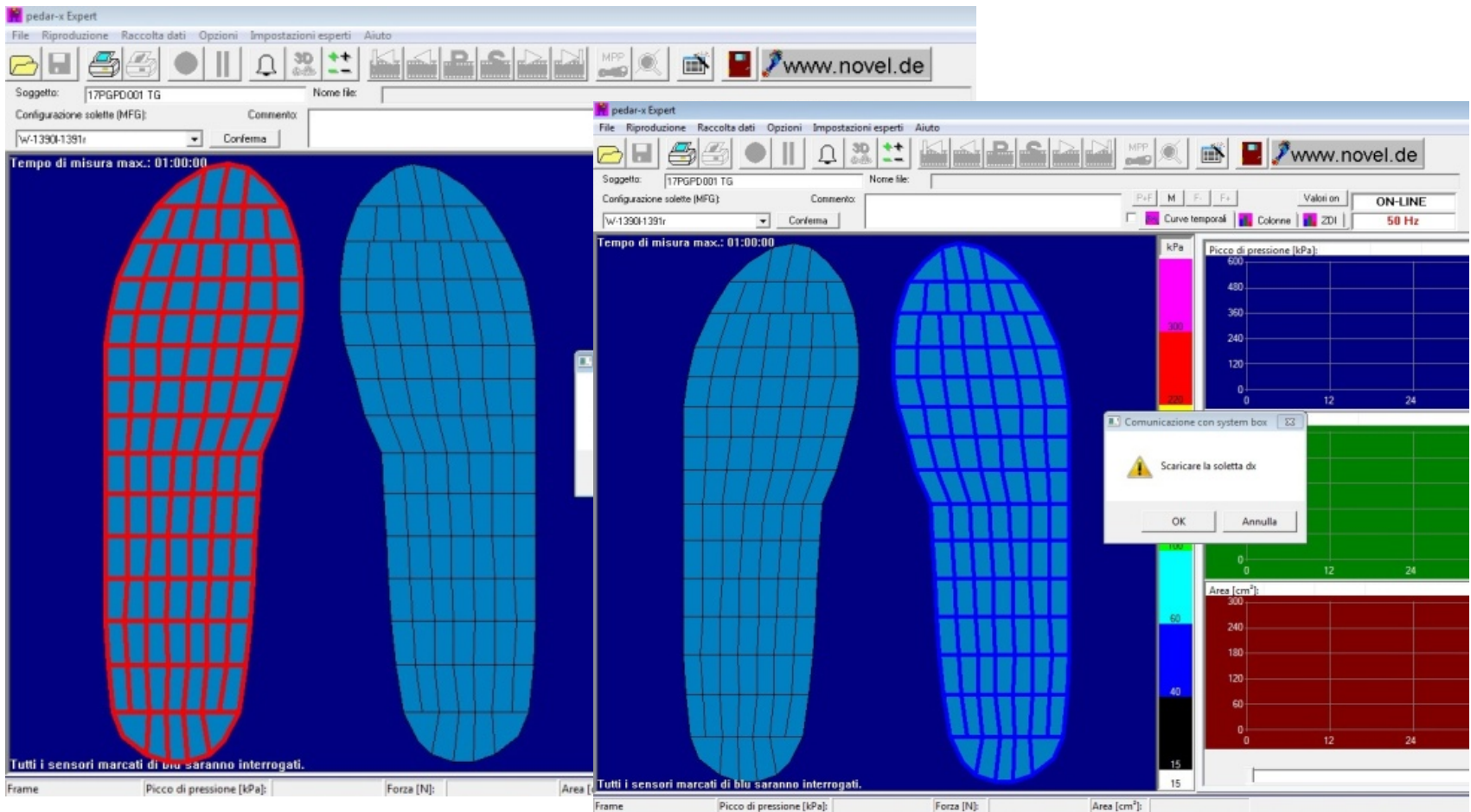
TEST EXECUTION AT T1 VISIT

- 3-Application of in-shoe dynamic plantar pressure insoles, measured using the PEDAR-X system (Novel GmbH, Munich, Germany).



TEST EXECUTION AT T1 VISIT

- 4-Preparation of sensorized insoles



TEST EXECUTION AT T1 VISIT

5-Static test execution

6-Test execution in dynamics

7-Removal of the multi-sensor insole system Pedar (Novel GmbH)

in neutral condition

TEST EXECUTION AT T1 VISIT

8-Impression taking

Seated subjects were positioned with their knee at 90° and ankle in a neutral position while the impressions were obtained.

The same examiner pressed the foot deeply into the foam box by stabilizing a subject's ankle and applying downward pressure from above the knee.

An additional push was then applied to the dorsum of the foot and toes.

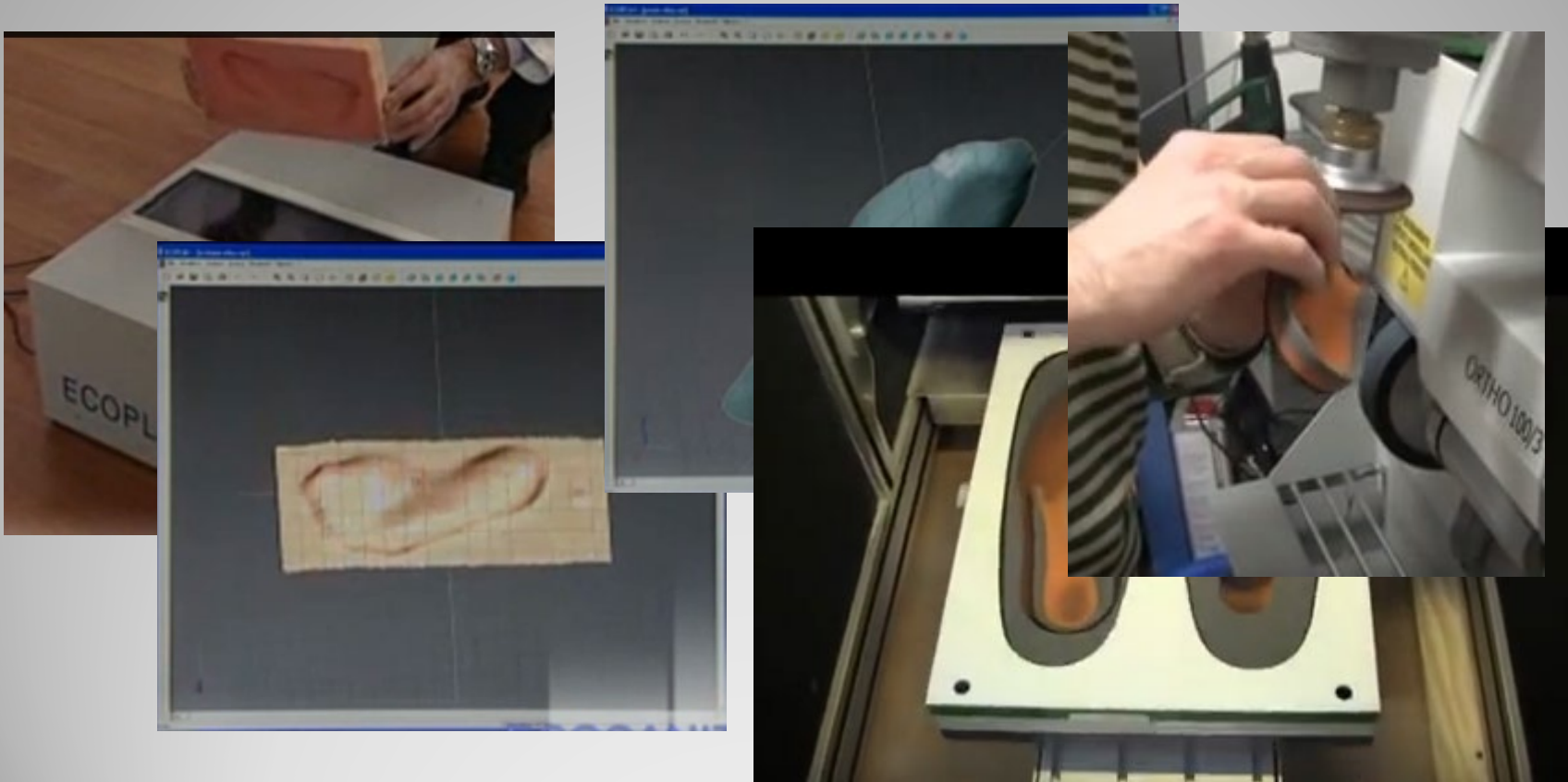
The foot was then removed from the foam, and the process was repeated with the opposite foot.



TEST EXECUTION AT T1 VISIT

The foam impressions were scanned using a 3D scanner (Guantificio Altotiberino ECOSANIT Calzature Snc, Anghiari (AR), Italy), and immediately sent to an orthotic supply company for the total contact custom insoles (TCCI) manufacture. The 3D scans were sent to a different orthotic company for CAD-CAM processing and creation of the custom milled insoles (CAD-CAM_CMI).

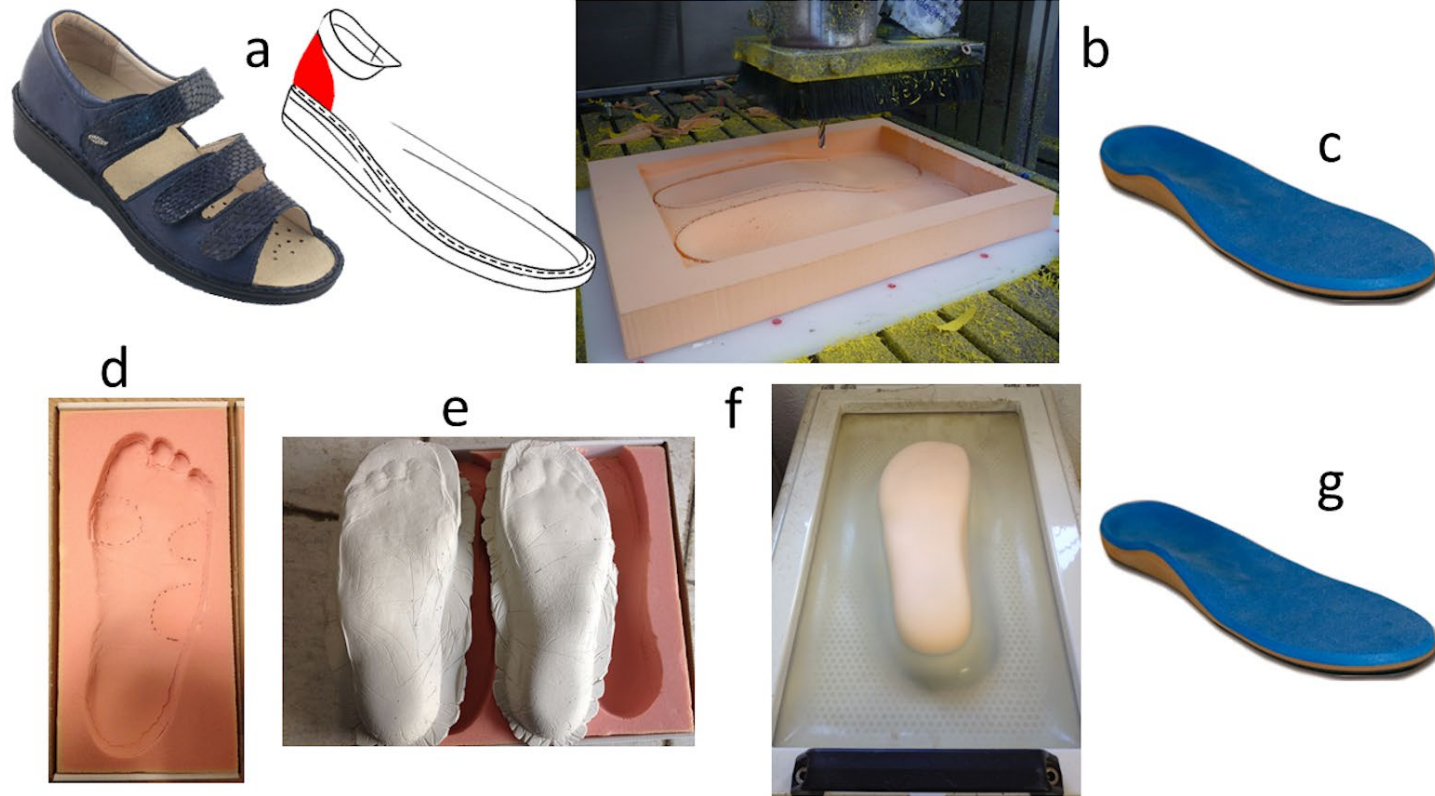
Cad-cam



■ Traditional shape- based total contact customised insoles (TCCI)



In the second session, the NFI was removed, and the same sandals were able to accommodate the custom-made insoles



According to the double-blind design, the coatings of the foot orthoses were visually indistinguishable. Hence, both the participant and the data recording operators were blind about the types of orthoses tested