AMD
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ASSOCIAZIONE MEDICI DIABETOLOGI

Approccio multidisciplinare alle complicanze del diabete:
IL PIEDE DIABETICO ACUTO

FORLÌ 31 MAGGIO 2024

Grand Hotel Forlì *- Via del Partigiano, 12 bis*

Off-loading prima durante e dopo la fase acuta

Daniela Piani

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Dipartimento Aziendale Cure Primarie - AUSL Modena

IWGDF Editorial Board

Practical Guidelines

Methodology and Management

8 members

Meetings and preparation
InGuide training
Methodology development
Process management
Writing
Peer review of all documents

collective years of full-time work:

2.5

IWGDF Guidelines: Working Group Members and External Experts

Prevention

Classification

Infection

PAD

Offloading

Wound healing

Charcot

Working Group Members and External Experts

119 experts involved

63 countries

Working Group Members

Meetings and preparation
InGuide training
Literature screening
Data extraction

collective years of full-time work: 5

Chair and Secretary

Meetings and preparation
InGuide training
Process management
Summary of findings tables
Evidence tables
Scientific writing

collective years of full-time work: 2.5

Systematic Reviews

120,477 Titles/abstracts screened

1,052 Full papers assessed

11 Systematic reviews

Guidelines

65 Clinical questions formulated

75 Critical outcomes selected

82 Summary of findings tables

142 Evidence-based recommendations

Together investing: 10 collective years in voluntary work

If these hours would have been properly financially compensated, this would have cost at least: 2 million Euros

LINEE GUIDA SULLA PREVENZIONE E GESTIONE DELLA MALATTIA DEL PIEDE CORRELATA AL DIABETE IWGDF 2023: cosa dicono in merito all'off-loading?

- Indicazione per l'utilizzo delle calzature per off-loading in prevenzione primaria
- Indicazione per l'utilizzo delle calzature per off-loading in fase acuta: ulcera neuropatica
- Indicazione per l'utilizzo delle calzature per off-loading in fase acuta: ulcera ischemica e/o infetta
- Indicazione per l'utilizzo delle calzature per off-loading in fase post-chirurgica

Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update)

Offloading è uno dei componenti chiave del protocollo di trattamento
di tutto lo spettro della malattia del piede correlata al diabete

Diabetes Metab Res Rev. 2024;e3651.

Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update)

RACCOMANDAZIONE		FORZA DELLA RACCOMANDAZIONE	GRADO DI EVIDENZA
1	SCREENING	FORTE	ALTA
2	ESAMINARE (lesioni pre-ulcerative, complicanze microvascolari, etc…)	FORTE	ALTA
3	EDUCARE a proteggere i piedi	FORTE	BASSA
4	EDUCARE all'igiene dei piedi	FORTE	BASSA
5	EDUCARE al controllo quotidiano	FORTE	BASSA
6	EDUCARE alla prevenzione	FORTE	BASSA
7	EDUCAZIONE & COACHING	FORTE	BASSA
8	**CALZATURE ADEGUATE/ SU MISURA/ TERAPEUTICHE**	**FORTE**	**BASSA**
9	TRATTAMENTO delle lesioni preulcerative	FORTE	MOLTO BASSA
10	**CHIRURGIA ORTOPEDICA PREVENTIVA**	**CONDIZIONATA**	**MEDIO-BASSA**
11	EVITARE decompressione del/dei nervi	CONDIZIONATA	MOLTO BASSA
12	ESERCIZIO FISICO 8-12 settimane	CONDIZIONATA	BASSA
13	COMUNICARE circa attività fisica, calzature, monitoraggio	CONDIZIONATA	BASSA
14	**CURA INTEGRATA DEL PIEDE: esame regolare del piede+ educazione strutturata+cura del piede professionale+ CALZATURE ADEGUATE**	**FORTE**	**BASSA**

Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update)

CATEGORIA DI RISCHIO	GRADO DI RISCHIO	ELEMENTI OBIETTIVI	CARATTERISTICHE CLINICHE	FREQUENZA CONTROLLO
0	MOLTO BASSO	PAD, LOPS	NESSUNO	12 mesi
1	BASSO	PAD, LOPS	1 dei due	6-12 mesi
2	MODERATO	PAD, LOPS, DEFORMITA' DEL PIEDE	ALMENO 2	3-6 mesi
3	ALTO	PAD oppure LOPS + • Storia di ulcere ai piedi • Amputazione minore o maggiore • ESRD	PAD oppure LOPS + almeno 1 dei seguenti	1-3 mesi

Diabetes Metab Res Rev 2024; e3651

Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update)

RACCOMANDAZIONE 8			FORZA	QUALITA’
In una persona con DIABETE e PIEDI A RISCHIO DI ULCERAZIONE				
A	Senza deformità ai piedi o deformità lievi Senza lesioni pre-ulcerative Senza storia di ulcerazioni ai piedi IWGDF rischio 1-3	Educare a utilizzare CALZATURE ADATTE alla forma del piede e che calzino in modo corretto	**FORTE**	**BASSA**
B	Con deformità del piede che aumentino significativamente le pressioni Con lesioni pre-ulcerative IWGDF rischio 2-3	Prescrivere CALZATURE con profondità extra, su misura, con plantari su misura e/o ortesi per le dita	**CONDIZIONATA**	**BASSA**
C	Con ulcera plantare guarita IWGDF rischio 3	**Prescrivere CALZATURE TERAPEUTICHE** (con caratteristiche che forniscano effetti terapeutici, non presenti nelle calzature comuni; su misura o prefabbricate)	**FORTE**	**MODERATA**

Practical Guidelines on the prevention and management of diabetes related foot disease (IWGDF 2023 update)

CARATTERISTICHE DELLE CALZATUTE DI MORFOLOGIA ADEGUATA ALLA PREVENZIONE DELL'ULCERA:

Nella persona con diabete senza ulcera del piede in atto occorre attuare 5 punti chiave:

3.4 nelle persone con categoria di rischio ≥ 1 incentivare l'utilizzo routinario di calzature appropriate

Lunghezza della calzatura > 1-2 cm rispetto alla lunghezza del piede, non troppo strette né troppo larghe

Di larghezza interna pari alla larghezza del piede a livello delle articolazioni MTTF

Con tomaia alta a sufficienza per alloggiare le dita

Indoors e outdoors

Per tutto il tempo

Se compaiono lesioni nel corso dell'uso di calzature appropriate, prescrivere **calzature terapeutiche (con tomaia più alta e costruite su misura, come pure il plantare)**

E' indicato fornire supporto finanziario per attuale queste indicazioni

Diabetes Metab Res Rev 2024; e3657

Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update)

RACCOMANDAZIONE 10 OFF LOADING CHIRURGICO		FORZA	QUALITA'
In una persona con DIABETE e PIEDI A RISCHIO DI ULCERAZIONE IWGDF rischio 1-3 • Con alluce NON rigido • Con alterazioni dell'unghia, callosità, lesioni pre-ulcerative distali o all'apice dell'alluce			
A	Considerare la **tenotomia del flessore digitale quale trattamento terapeutico delle lesioni in atto e prevenzione ex novo o della ricorrenza delle lesioni**	**CONDIZIONATA**	**MEDIA**
B	Considerare la prescrizione di ortesi tipo devices in silicone o semi-rigidi per l'alluce per ridurre le callosità	**CONDIZIONATA**	**BASSA**

Guidelines on the classification of foot ulcers in people with diabetes (IWGDF 2023 update)

Wound, Ischemia, and Foot Infection (WIfI) Classification of Limb Threat

The Wound, Ischemia, and Foot Infection (WIfI) classification system consists of 3 components graded separately from 0 (none) to 3 (severe).

One component may be dominant but the specific combination of scores is used to estimate the risk of limb amputation at 1 year and the need for or benefit of revascularization.[a]

Wound (W)

Grade	Ulcer	Gangrene
0	None	None
1	Small, shallow	None
2	Deep with exposed bone, joint, or tendon	Limited to digits
3	Extensive, deep, and involving forefoot and/or midfoot with or without calcaneal involvement	Extensive and involving forefoot and/or midfoot Full thickness heel necrosis with or without calcaneal involvement

Ischemia (I)

Grade	Ankle-brachial index Ankle systolic pressure	Toe pressure or transcutaneous oximetry
0	≥0.80 >100 mm Hg	≥60 mm Hg
1	0.60-0.79 70-100 mm Hg	40-59 mm Hg
2	0.40-0.59 50-69 mm Hg	30-39 mm Hg
3	≤0.39 <50 mm Hg	<30 mm Hg

Foot infection (fI)

Grade	Clinical manifestation
0	No symptoms or signs of infection
1	Infection indicated by ≥2 of the following: • Local swelling or induration • Erythema 0.5-2.0 cm around ulcer • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white, or sanguineous)
2	Infection as described above with: • Erythema >2 cm around ulcer • Involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis) • No signs of systemic inflammatory response (see below)
3	Infection as described above with ≥2 signs of systemic inflammatory response syndrome: • Temperature >38 °C or <36 °C • Heart rate >90/min • Respiratory rate >20/min or $PaCO_2$ <32 mm Hg • White blood cell count >12 000/μL or <4000/μL or 10% immature forms

SINBAD system.

Category	Definition	Score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischaemia	Pedal blood flow intact: at least one palpable pulse	0
	Clinical evidence of reduced pedal flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area Ulcer	Ulcer <1 cm^2	0
	Ulcer ≥1 cm^2	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total possible score		0–6

Jama 2023;330 (1): 62-75

Guidelines on the classification of foot ulcers in people with diabetes (IWGDF 2023 update)

IDSA/IWGDF system.

Clinical manifestations	Infection severity	PEDIS grade
Wound lacking purulence or any manifestations of inflammation	Uninfected	1
Presence of ≥2 manifestations of inflammation (purulence, or erythema, tenderness, warmth, or induration), but any cellulitis/erythema extends ≤2 cm around the ulcer, and infection is limited to the skin or superficial subcutaneous tissues; no other local complications or systemic illness	Mild	2
Infection (as above) in a patient who is systemically well and metabolically stable but which has ≥1 of the following characteristics: Cellulitis extending >2 cm, lymphangitic streaking, spread beneath the superficial fascia, deep-tissue abscess, gangrene, and involvement of muscle, tendon, joint or bone	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (e.g. fever, chills, tachycardia, hypotension, confusion, vomiting, leucocytosis, acidosis, severe hyperglycaemia, or azotaemia)	Severe	4

Jama 2023;330 (1): 62-75

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

	TIPOLOGIA ULCERA	SEDE	CONDIZIONE	RACCOMANDAZIONE	FORZA	QUALITA
3	**NEUROPATICA**	Avampiede/ Mediopiede/ retropiede	ULCERA IN ATTO	STOP!!!! Calzature comuni (di serie, senza indicazioni terapeutiche) Calzature terapeutiche standard (pret-a-porter, con indicazioni terapeutiche, ma senza adattamento al piede del paziente	**FORTE**	**BASSA**

Diabetes Metab Res Rev. 2024;e3647

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

	TIPOLOGIA ULCERA	SEDE PLANTARE	CONDIZIONE	RACCOMANDAZIONE	FORZA	QUALITA
1 a,b	**NEUROPATICA**	Avampiede/ mediopiede		Ortesi alta al ginocchio – non rimovibile : TCC oppure walker alto al ginocchio, non-rimovibile	**FORTE** **CONDIZIONATA**	**MEDIA** **MEDIA**

Non-removable Offloading Devices

- Total Contact Cast
- "Non-removable" Controlled Ankle Motion (CAM) boot

Controlled Ankle Motion (CAM) boot

- Rendered irremovable by applying a layer of cast or tie wrap around the device.

Diabetes Metab Res Rev. 2024;e3647

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

	TIPOLOGIA ULCERA	SEDE PLANTARE	CONDIZIONE	RACCOMANDAZIONE	FORZA	QUALITA
2	**NEUROPATICA**	Avampiede/ mediopiede	Se Ortesi alta al ginocchio – non rimovibile è controindicata o non tollerata	walker alto al ginocchio, rimovibile OPPURE walker alto alla caviglia	**CONDIZIONATA**	**BASSA**
4	**NEUROPATICA**	Avampiede/ mediopiede	NON disponibilità di offloading devices	CALZATURE ADEGUATE + schiuma di feltro	**CONDIZIONATA**	**BASSA**

Diabetes Metab Res Rev. 2024;e3647

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

	TIPOLOGIA ULCERA	SEDE PLANTARE	CONDIZIONE	RACCOMANDAZIONE	FORZA	QUALITA
5a	**NEUROPATICA**	MTT	Fallimento dell'offloading non chirurgico	Allungamento del tendine di Achille + offloading devices	**CONDIZIONATA**	**MEDIA**
5b		MTT	Fallimento dell'offloading non chirurgico	Resezione delle teste MTT + offloading devices	**CONDIZIONATA**	**BASSA**
5c		ALLUCE	Fallimento dell'offloading non chirurgico	Artroplastica articolare + offloading devices	**CONDIZIONATA**	**BASSA**
5d		MTT	Fallimento dell'offloading non chirurgico	Osteotomia MTT + offloading devices	**CONDIZIONATA**	**MOLTO BASSA**
6		DIGITALE 2-5 APICALE	Deformità riducibile del dito	Tenotomia del flessore digitale	**FORTE**	**MEDIA**

Diabetes Metab Res Rev. 2024;e3647

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

- Percutaneous Flexor Tenotomy

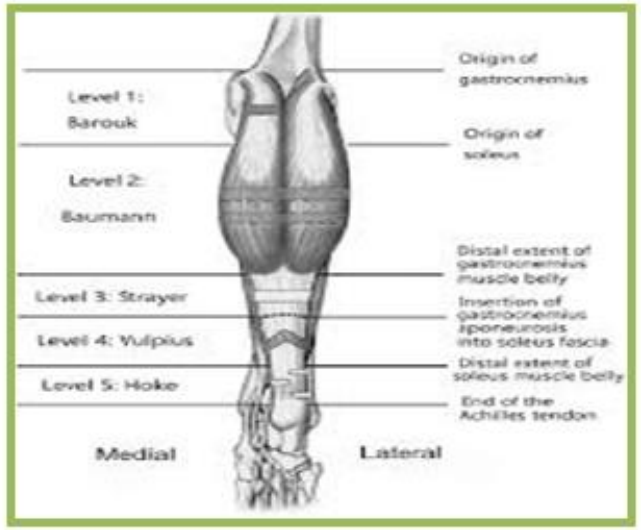
References:

- *Scott JE, Hendry GJ, Locke J. Effectiveness of percutaneous flexor tenotomies for the management and prevention of recurrence of diabetic toe ulcers: a systematic review. J Foot Ankle Res. 2016;9:25.*
- *Kearney TP, Hunt NA, Lavery LA. Safety and effectiveness of flexor tenotomies to heal toe ulcers in persons with diabetes. Diabetes Res Clin Pract. 2010;89(3):224-6*
- *Laborde JM. Neuropathic toe ulcers treated with toe flexor tenotomies. Foot Ankle Int. 2007;28(11):1160-4.*
- *Rasmussen A, Bjerre-Christensen U, Almdal TP, Holstein P. Percutaneous flexor tenotomy for preventing and treating toe ulcers in people with diabetes mellitus. J Tissue Viability. 2013;22(3):68-73.*
- *Tamir E, Vigler M, Avisar E, Finestone AS. Percutaneous tenotomy for the treatment of diabetic toe ulcers. Foot Ankle Int. 2014;35(1):38-43.*
- *van Netten JJ, Bril A, van Baal JG. The effect of flexor tenotomy on healing and prevention of neuropathic diabetic foot ulcers on the distal end of the toe. J Foot Ankle Res. 2013;6(1):3.*
- *Tamir E, McLaren AM, Gadgil A, Daniels TR. Outpatient percutaneous flexor tenotomies for management of diabetic claw toe deformities with ulcers: a preliminary report. Can J Surg. 2008;51(1):41-4.*

Diabetes Metab Res Rev. 2024;e3647

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

- Gastrocnemius recession/Achilles
  - Baumann
  - Strayer
  - Endoscopic gastroc recession
  - Triple hemi-section



Reference: Kai Rong, Wen-tao Ge, Xing-chen Li, and Xiang-yang Xu. Mid-term Results of Intramuscular Lengthening of Gastrocnemius and/or Soleus to Correct Equinus Deformity in Flatfoot. James Hill, DPM FACFAS

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

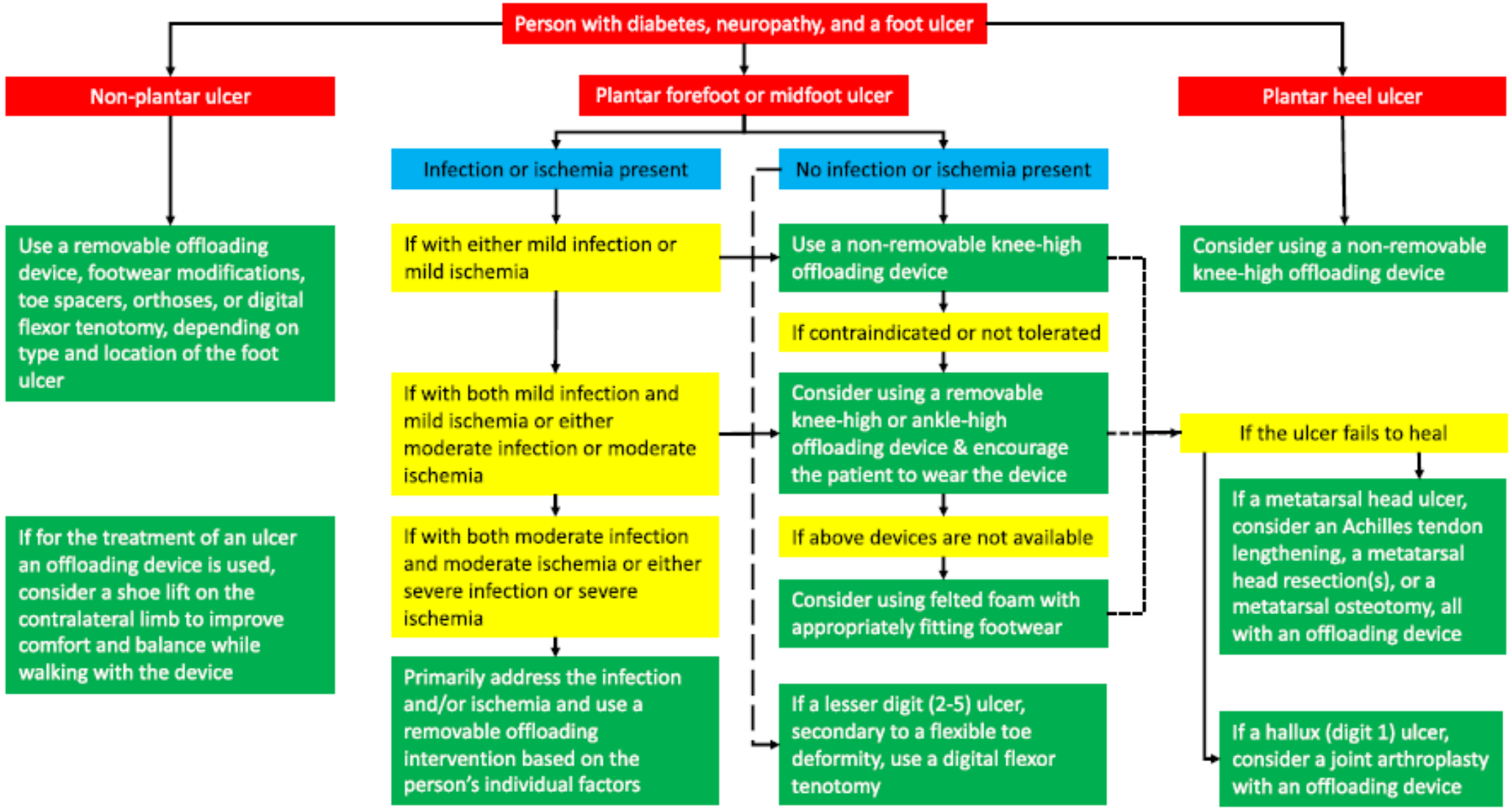
	TIPOLOGIA ULCERA	SEDE	CONDIZIONE	RACCOMANDAZIONE	FORZA	QUALITA
8	**NEUROPATICA**	Retropiede PLANTARE		Ortesi alta al ginocchio – non rimovibile, PREFERIBILE!	**CONDIZIONATA**	**MOLTO BASSA**
9	NEUROPATICA NON- PLANTARE			Offloading device rimovibili Calzature modificate Spaziatori per dita Tenotomia del flessore dorsale	**FORTE**	**MOLTO BASSA**
10	ULCERA AL PIEDE in terapia con device di scarico alto al ginocchio			Considerare l'uso di un rialzo per la calzatura controlaterale	**CONDIZIONATA**	**MOLTO BASSA**

Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

	TIPOLOGIA ULCERA	SEDE PLANTARE	CONDIZIONE	RACCOMANDAZIONE	FORZA	QUALITA
7a	**NEUROPATICA**	Avampiede/ mediopiede	INFEZIONE O ISCHEMIA **LIEVI**	Ortesi alta al ginocchio – non rimovibile	**CONDIZIONATA**	**BASSA**
7b	**NEUROPATICA**	Avampiede/ mediopiede	INFEZIONE O ISCHEMIA **MODERATE**	Ortesi rimovibile	**CONDIZIONATA**	**BASSA**
7c	**NEUROPATICA**	Avampiede/ mediopiede	INFEZIONE O ISCHEMIA **SEVERE**	Ortesi rimovibile	**FORTE**	**MOLTO BASSA**

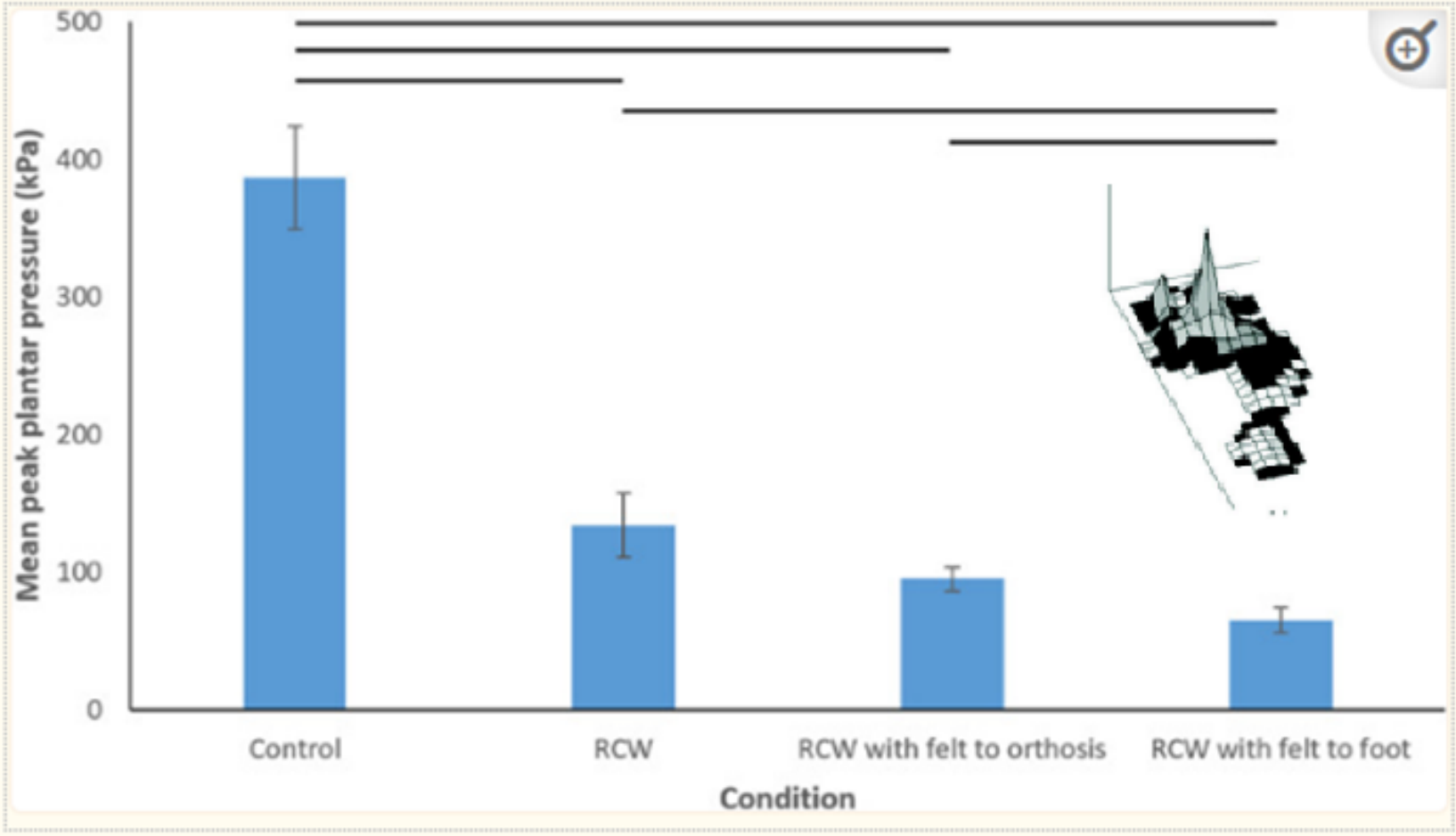
Diabetes Metab Res Rev. 2024;e3647

Flow diagram on the recommended offloading treatment for a person with **diabetes and a foot ulcer**



Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

Footwear and insole design features for offloading the diabetic at risk foot—
A systematic review and meta-analyses



Comparison of mean peak plantar pressures for the control and three removable cast walkers (RCWs) – error bars are standard errors and horizontal lines at top of graph indicate statistically significant differences between two conditions

New: 2023 Offloading recommendations

Peter Lazzarini -Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

Key considerations

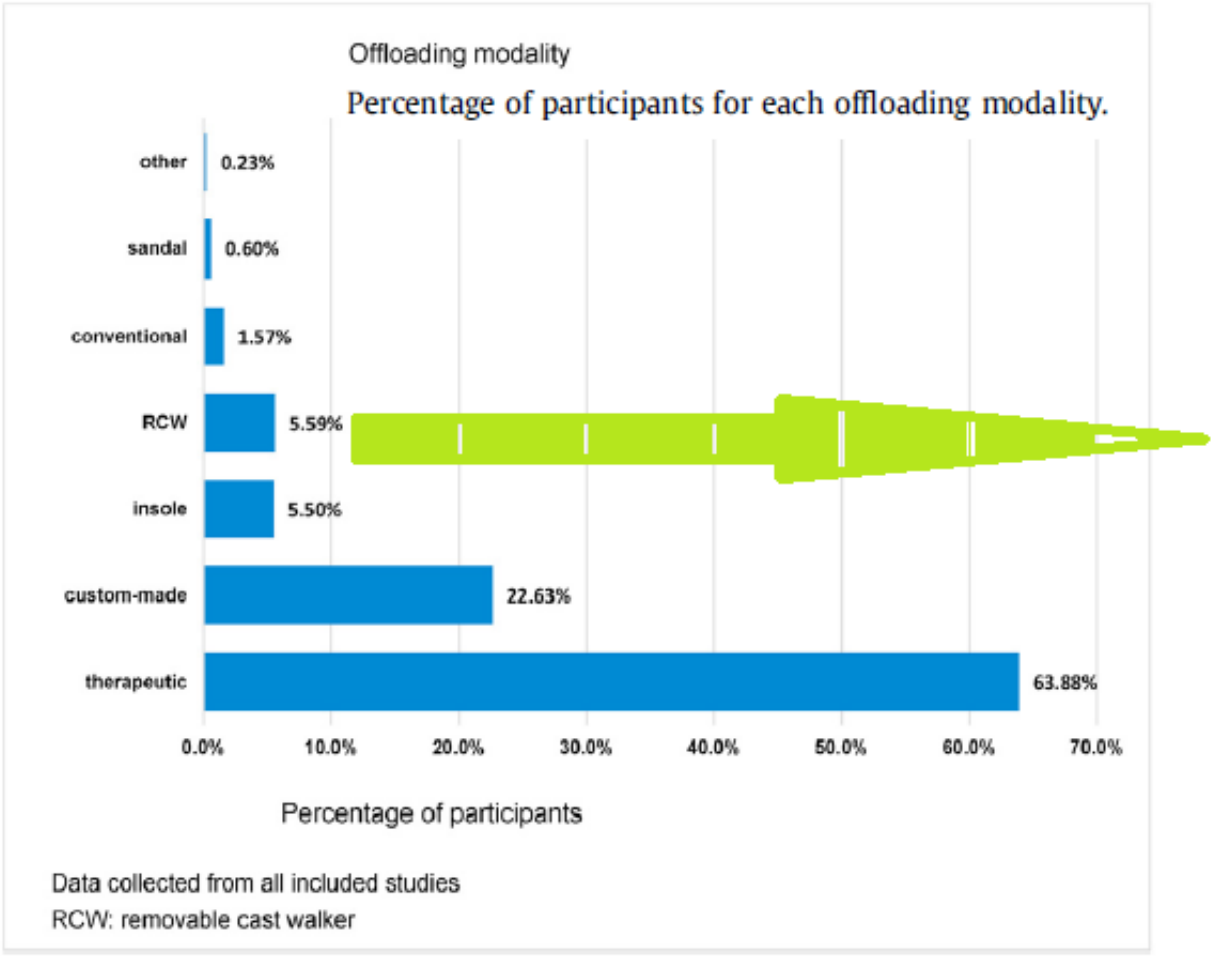
- Robust data are lacking on whom, how, and when to screen for ulcer risk
- High quality data on interventions to prevent a first foot ulcer are scarce
- Costs and cost-effectiveness of intervention needs more research
- Adherence to an intervention is crucial in outcomes

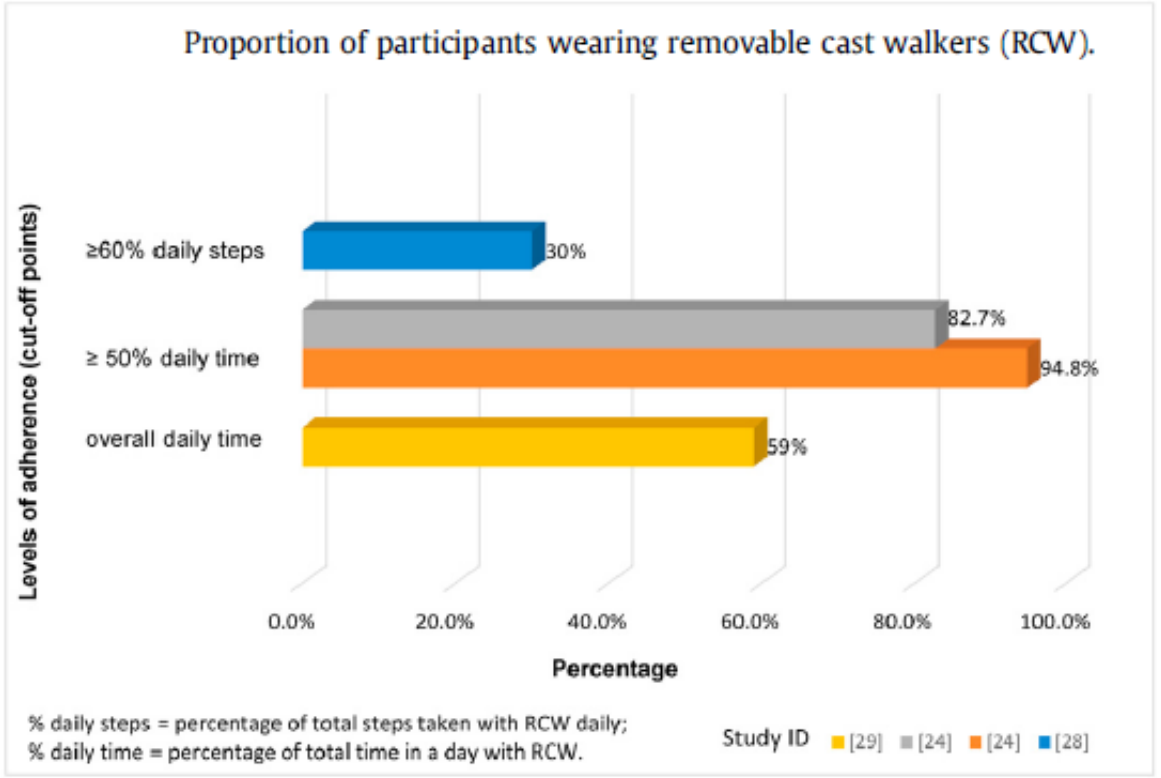
-Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2023 update)

Reviews and Meta-analysis

Offloading treatment in people with diabetic foot disease: A systematic scoping review on adherence to foot offloading

Simona Racaru, MSc a, b, *, Layla Bolton Saghdaoui, BSc a, Jaya Roy Choudhury, MBBS c, Mary Wells, PhD d, Alun H. Davies, DSC FRCS





Diabetes & Metabolic Syndrome: Clinical Research & Reviews 16 (2022) 102493

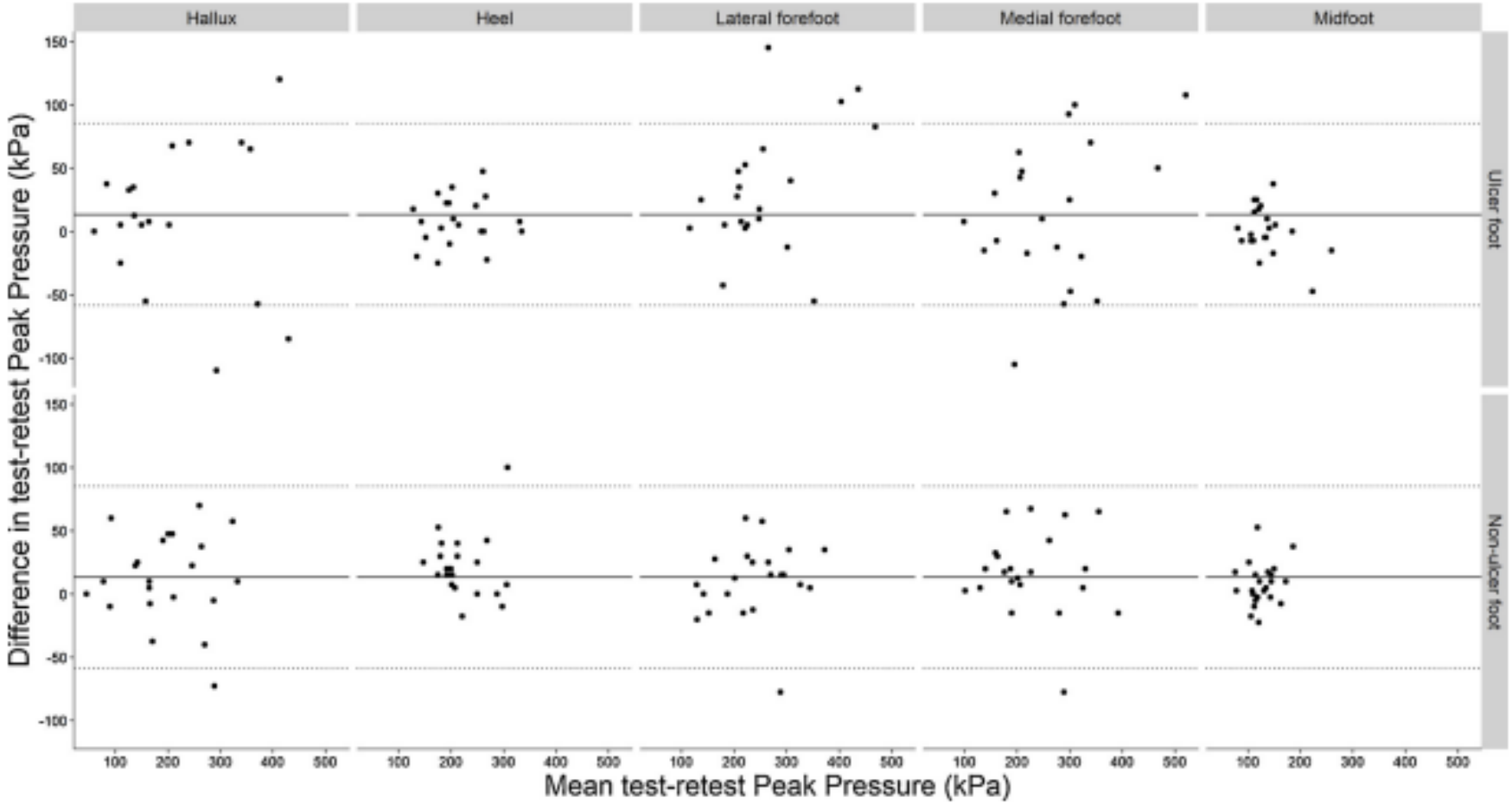
Footwear and insole design features for offloading the diabetic at risk foot—
A systematic review and meta-analyses

PRINICIPALI OBIETTIVI DELL'OFFLOADING:

- Ridurre le pressioni plantari di picco
- Ridurre le pressioni plantari medie e il gradiente di pressione nei punti critici (Integrale pressioneTempo, variazione spaziale nella PP intorno al punto PPP)
- Ri-distribuire i carichi pressori
- Aumentare la velocità dei tempi di transizione del passo
- Favorire l'equilibrio durante la fase intermedia del passo
- Ridurre lo shear stress

J Foot Ankle Res. 2023; 16: 27..

Reliability of peak foot pressure in patients with previous diabetic foot ulceration



Bland-Altman plot of the difference in test-retest peak pressure (kPa) against the mean of the test-retest peak pressure (kPa) for the different foot regions, grouped by the foot with the primary foot ulcer (Ulcer foot) and the opposite foot (Non-ulcer foot).

Gait & Posture 2019;70:6-11.

Analysis of Plantar Pressure Pattern after Metatarsal Head Resection. Can Plantar Pressure Predict Diabetic Foot Reulceration?

Patients who underwent a minor metatarsal head resection (second–fifth metatarsal heads) showed a **medial transference of pressure.**

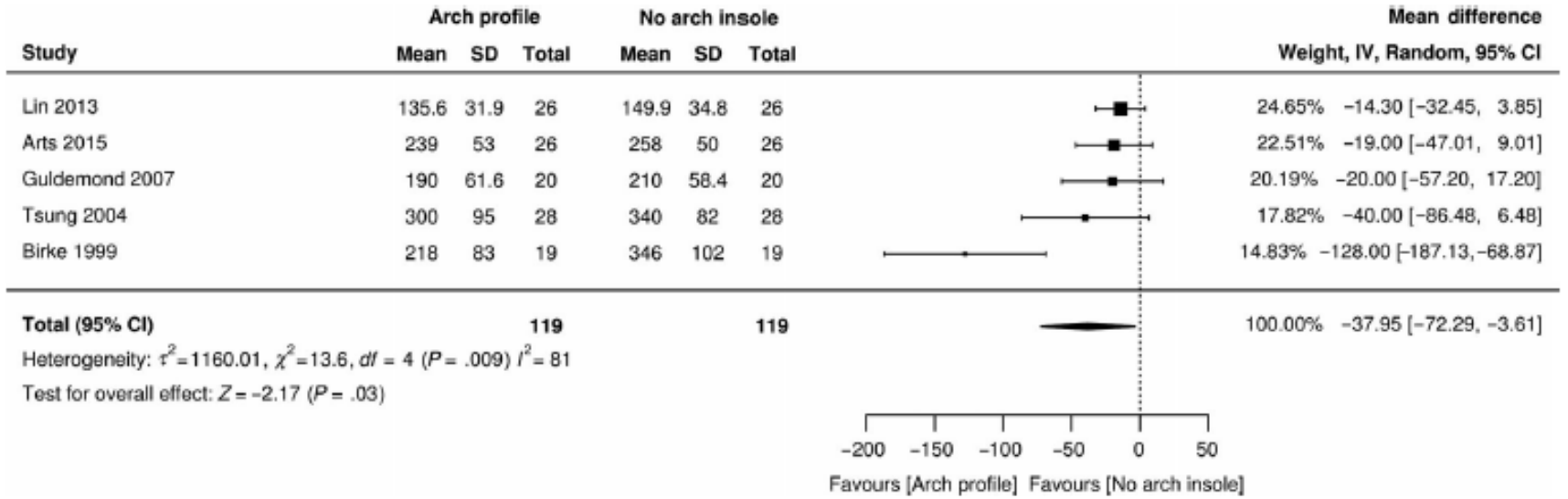
Additionally, following the resection of the first metatarsal head there was a **transference of pressure beneath the 2nd metatarsal head.**

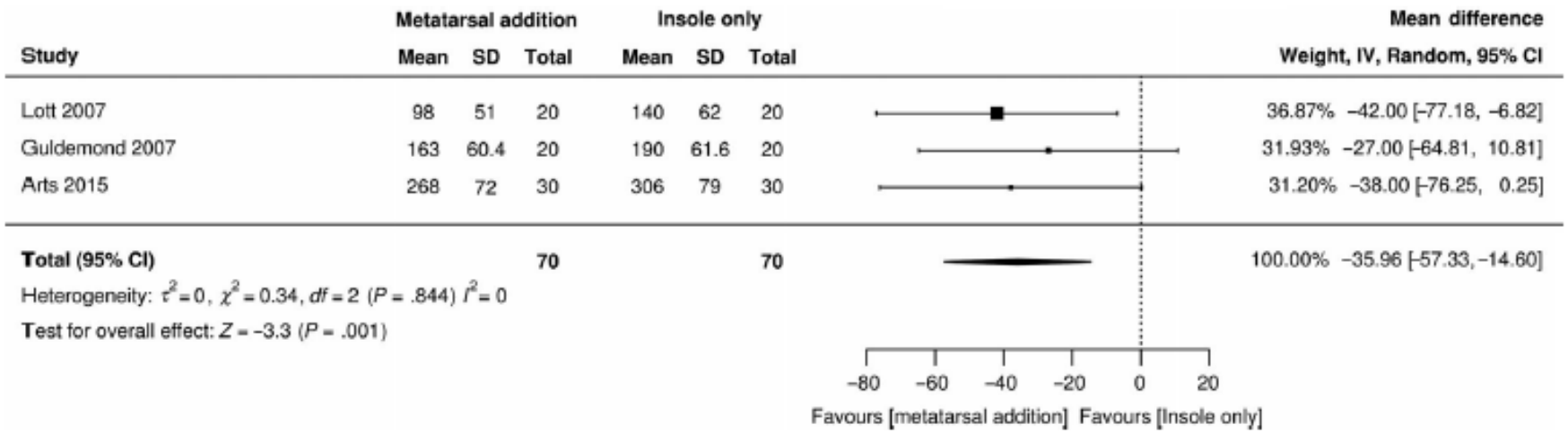
Increase of pressure was found to be a predictor of reulceration in cases of resection of the first and second metatarsal heads.

J. Clin. Med. 2021, 10, 2260. https://doi.org/10.3390/jcm10112260.

Footwear and insole design features for offloading the diabetic at risk foot—
A systematic review and meta-analyses

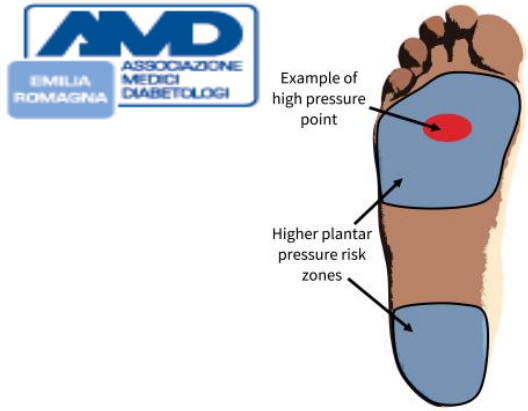
PLANTARE

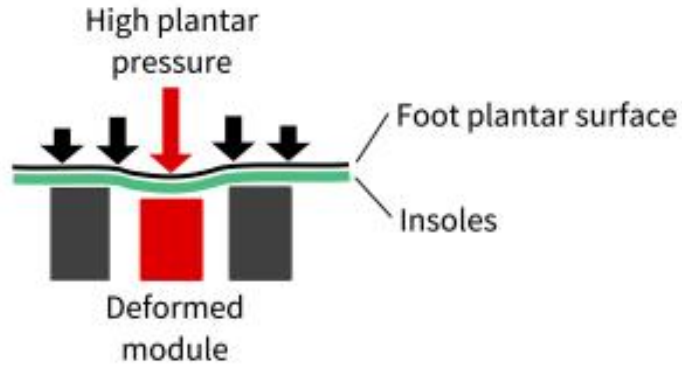




Endocrinol Diab Metab. 2021;4:e00132.

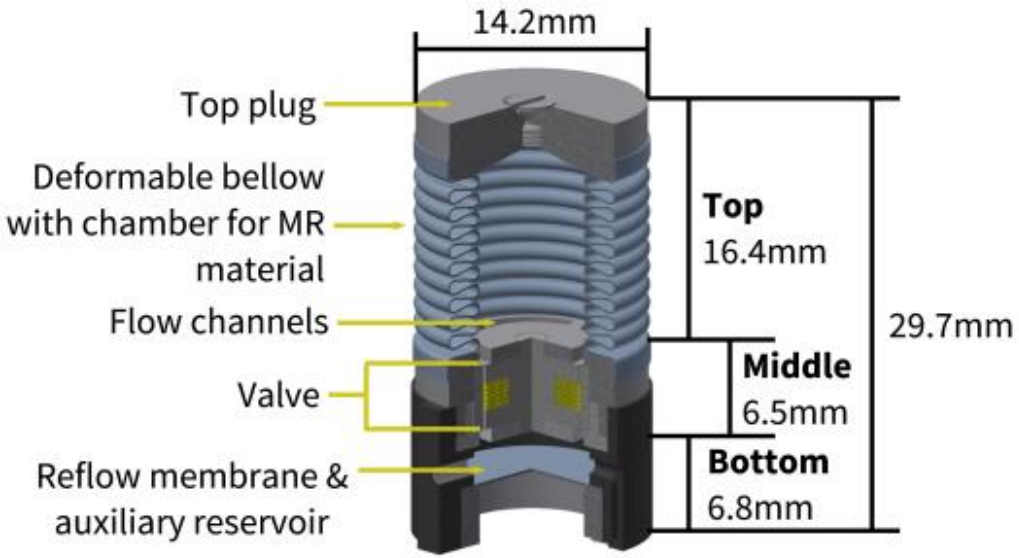
Intelligent plantar pressure offloading for the prevention of diabetic foot ulcers and amputations

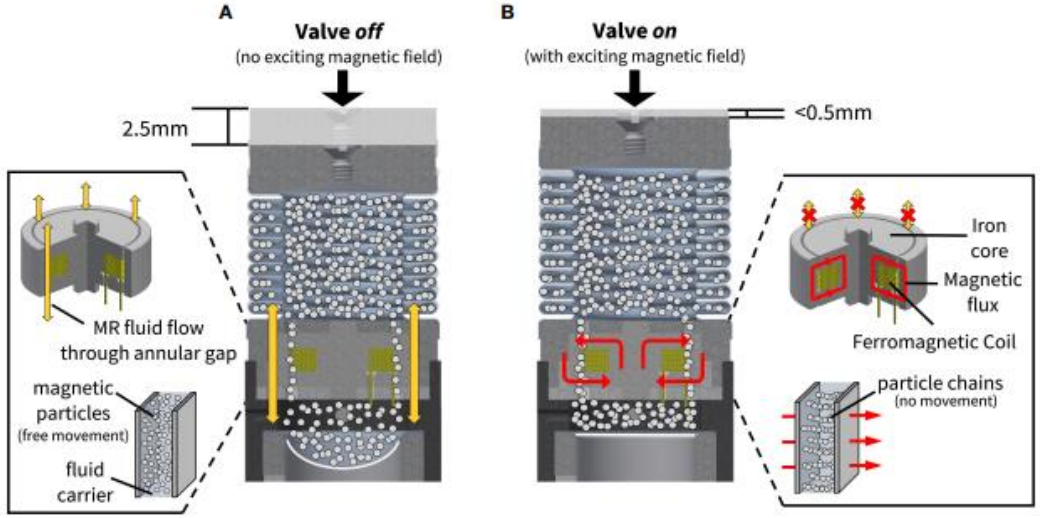


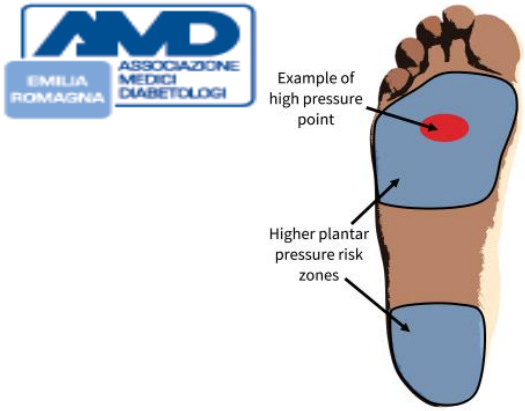


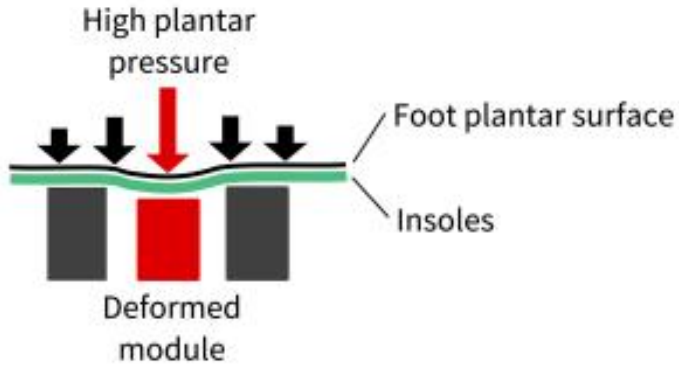
Front. Endocrinol. 14:1166513. doi: 10.3389/fendo.2023.1166513

Intelligent plantar pressure offloading for the prevention of diabetic foot ulcers and amputations









Front. Endocrinol. 14:1166513. doi: 10.3389/fendo.2023.1166513

Footwear and insole design features for offloading the diabetic at risk foot—
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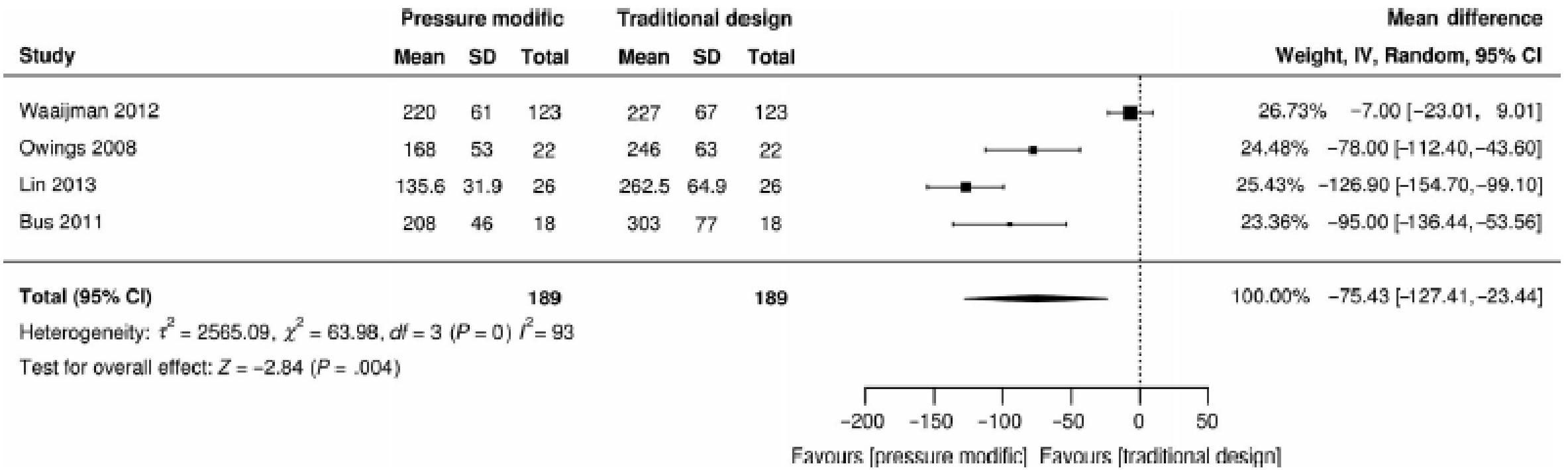
TECNICHE E MATERIALI DI COSTRUZIONE DI CALZATURE, SUOLE E PLANTARI



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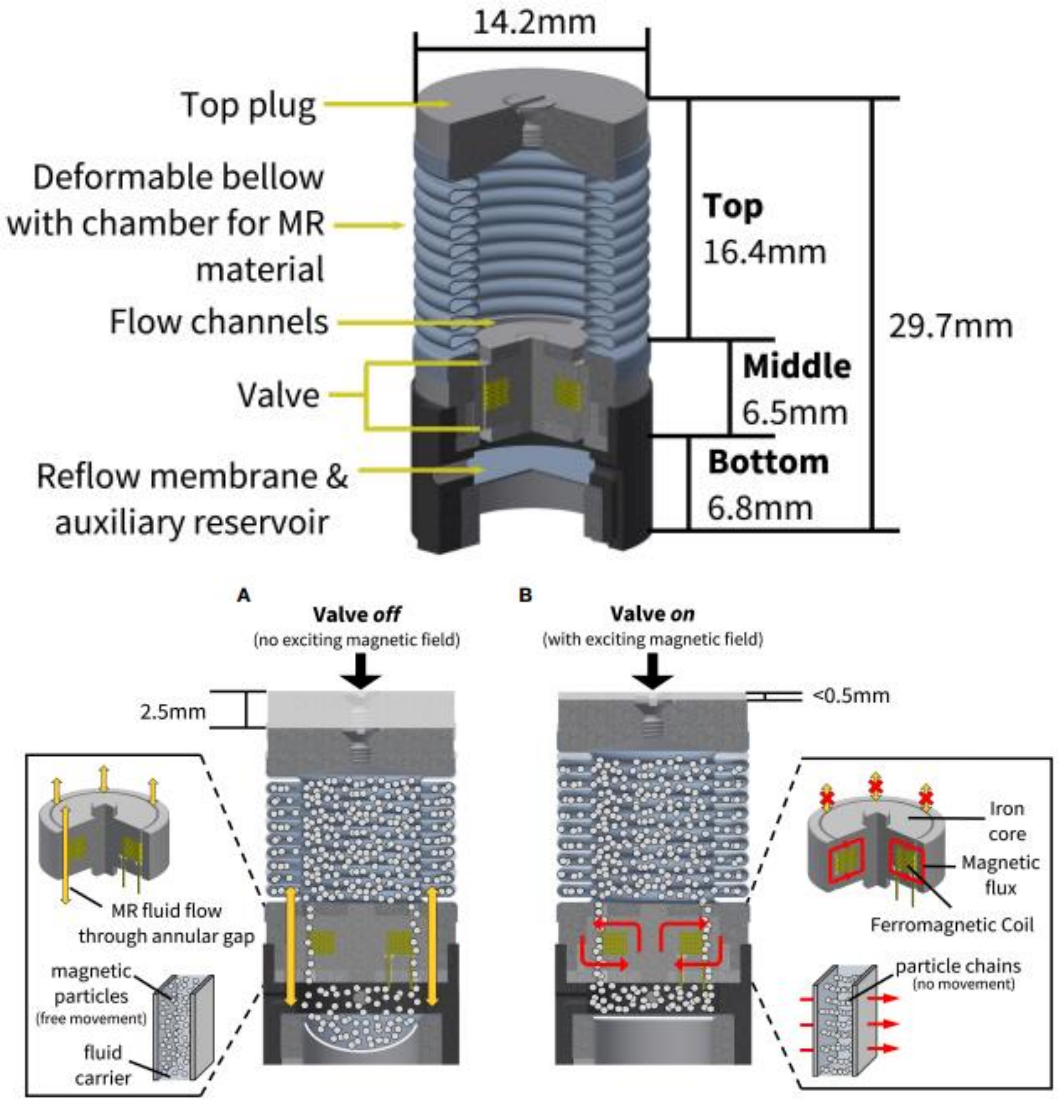
Footwear and insole design features for offloading the diabetic at risk foot—
A systematic review and meta-analyses



Endocrinol Diab Metab. 2021;4:e00132.

Offloading systems for the treatment of neuropathic foot ulcers in patients with diabetes mellitus: a meta-analysis of randomized controlled trials for the development of the Italian guidelines for the treatment of diabetic foot syndrome

SI RACCOMANDANO:

SUOLA rocker?

PLANTARE ad arco, multistrato, con analisi e modificazione delle pressioni plantari, con aggiunta di devices metatarsali

PROBABILMENTE QUALUNQUE sistema di offloading favorisce la guarigione dell'ulcera neuropatica al piede rispetto all'assenza di offloading o al mancato uso di calzature terapeutiche

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