

L'OFFLOADING NELLA FASE ACUTA

Dott. Maurizio Gicchino

*Azienda Ospedaliera Universitaria
Università degli studi della Campania L. Vanvitelli
U.O.C di Endocrinologia e Malattie del Metabolismo
Prof. Katherine Esposito*

*Centro per la prevenzione, diagnosi e cura
del piede diabetico*



Lo scarico del piede diabetico

Fase Pre - Ulcerativa	Fase Ulcerativa	Fase post-ulcerativa
CALZATURA IN PREVENZIONE PRIMARIA	TOTAL CONTACT CAST O TUTORI DI SCARICO CON PLANTARI ADATTATI ALLA LESIONE	CALZATURA IN PREVENZIONE SECONDARIA

TERAPIA AD-HOC IN BASE AL TIPO DI DFU

Nelle lesioni ischemiche la
priorità è il ripristino del
flusso



RIVASCOLARIZZAZIONE

Nelle lesioni infette la
priorità è la risoluzione
dell'infezione



DEBRIDEMENT +
ANTIBIOTICOTERAPIA

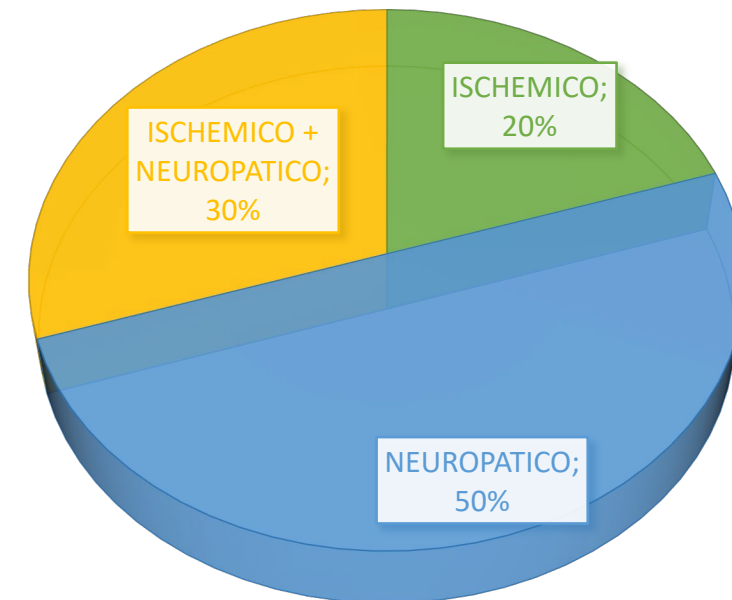
Nelle lesioni neuropatiche la
priorità è rimodulare lo
scarico delle pressioni



CORRETTO OFFLOADING

MA QUALI E QUANTE SONO LE DFU NEUROPATICHE?

PIEDE	ISCHEMICO	NEUROPATICO
CUTE	SOTTILE	IPERCHERATOSI
COLORITO	PALLIDO	SCURO
TEMPERATURA	FREDDO	CALDO
VENE	ESILI	TURGIDE
ASPETTO	ATROFICO	DEFORME
POLSI	RIDOTTI	PRESENTI



Le Ulcere Neuropatiche

- Colpiscono circa il 19-35% delle persone con diabete mellito (DM)
- La frequenza sta aumentando con l'aumento annuale dell'incidenza del diabete mellito di tipo 2.
- Sono correlate alla polineuropatia diabetica sottostante (DPN)
- Le NU sono la causa principale di amputazione non traumatica degli arti inferiori negli Stati Uniti (USA), il 15% delle persone affette da NU richiedono l'amputazione dell'arto
- Inoltre, le NU sono responsabili di ospedalizzazioni prolungate, aumenti dei costi sanitari, diminuzione della qualità della vita e aumento delle tassi di mortalità



Neuropathic ulcers: a focused review

Brittany Urso MD, Mondana Ghias MD, Anan John MD, Amor Khachemoune MD, FAAD, FACMS

First published: 17 December 2020 <https://doi.org/10.1111/ijd.15362>

Etiology, Epidemiology, and Disparities in the Burden of Diabetic Foot Ulcers

Katherine McDermott, Michael Fang, Andrew J.M. Boulton, Elizabeth Selvin, and Caitlin W. Hicks

Diabetes Care 2023;46(1):209–221 | <https://doi.org/10.2337/dci22-0043>

Etiology, Epidemiology, and Disparities in the Burden of Diabetic Foot Ulcers

Katherine McDermott, Michael Fang, Andrew J.M. Boulton, Elizabeth Selvin, Caitlin W. Hicks

Diabetic foot ulcer (DFU) is a common, highly morbid complication of diabetes and a critical step in the pathway to lower-extremity amputation (LEA). LEA rates are increasing after a period of previous decline. Racial and ethnic minorities and people with socioeconomic disadvantage affected by DFU are at a disproportionately high risk of LEA and mortality.

DFU prevalence is increasing as persons with diabetes live longer

PN PAD/CVD CKD Retinopathy



19%-34% lifetime risk of DFU

People with DFU are at high risk of LEA, especially young, racial/ethnic minority, and low-SES groups



20% of people with DFU require LEA



LEA increasing in last 5-10 years

Better diabetes preventive care is necessary to decrease incidence of DFU and LEA



Preventive visits CV risk management A1C testing and glucose management



La prevalenza sia del DFU che dell'amputazione degli arti inferiori correlata al diabete sta aumentando, soprattutto tra i giovani con diabete. Persistono forti disparità razziali, etniche e socioeconomiche nella cura del DFU.

Sono necessari miglioramenti su larga scala nella prevenzione e nello screening del piede per ridurre i tassi di DFU e di amputazione degli arti inferiori.

LA PREVENZIONE DEL PIEDE DIABETICO PASSA DA QUI



REVIEW ARTICLE

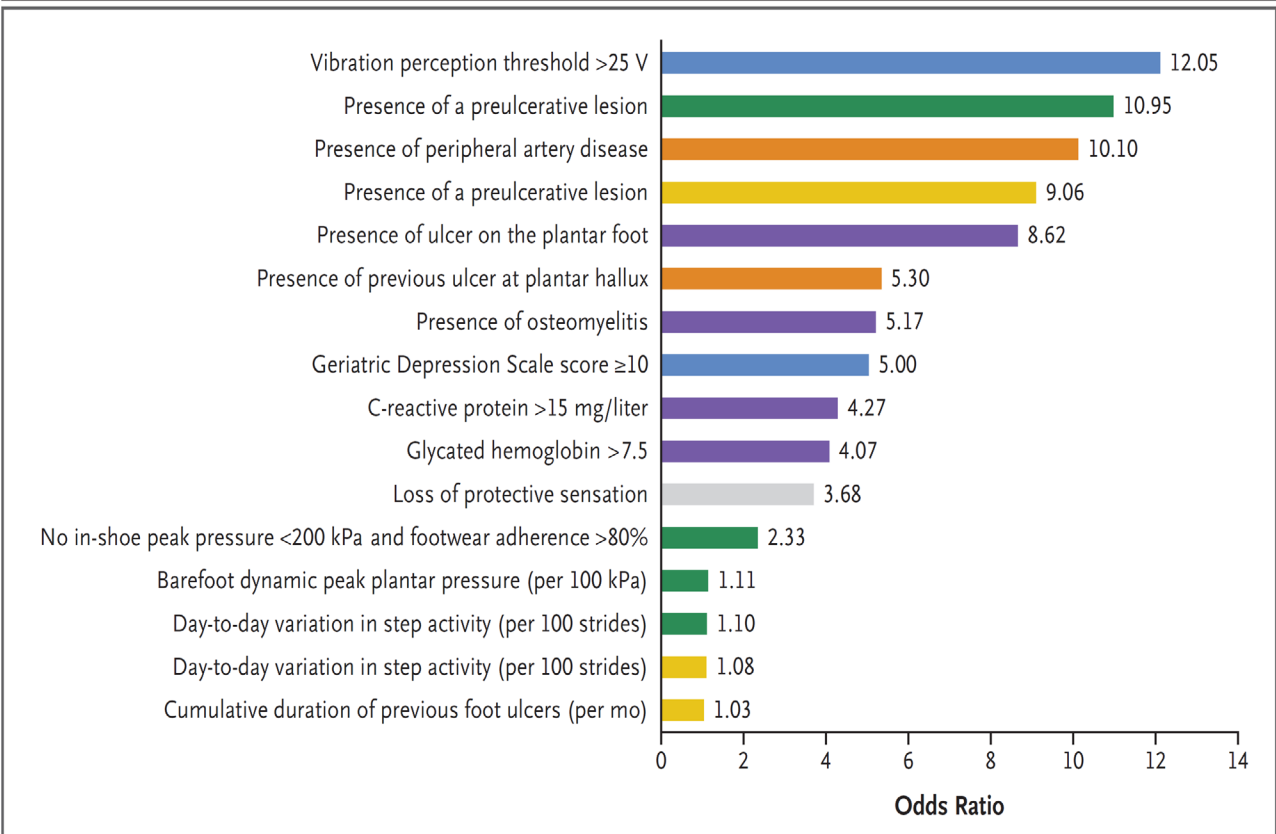
Julie R. Ingelfinger, M.D., *Editor*

Diabetic Foot Ulcers and Their Recurrence

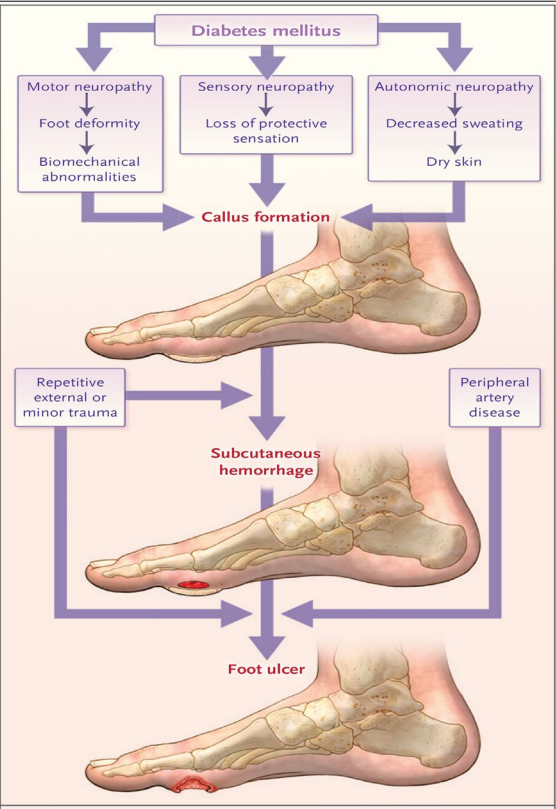
David G. Armstrong, D.P.M., M.D., Ph.D., Andrew J.M. Boulton, M.D.,
and Sicco A. Bus, Ph.D.

Figure 3. Risk Factors Independently Associated with Ulcer Recurrence.

Data are from five studies that reported an odds or risk ratio.^{28,33,42,52,56} According to Monami et al.⁴² (blue), risk factors for ulcer recurrence are a vibration perception threshold greater than 25 V and a Geriatric Depression Scale score of 10 or higher (scores range from 0 to 15, with higher scores indicating more severe depression). According to Peters et al.³⁶ (orange), risk factors for ulcer recurrence are the presence of peripheral artery disease and location of the previous ulcer at the plantar hallux. According to Dubský et al.²⁸ (purple), a plantar location of the ulcer, the presence of osteomyelitis, and elevated blood levels of C-reactive protein and glycated hemoglobin (all of which were determined at the time of study enrollment for patients with an active foot ulcer) are independent predictors of recurrence of foot ulcers. According to Reiber et al.³³ (gray), loss of protective sensation is a risk factor for recurrence of an ulcer on the plantar surface of the foot. According to Waaijman et al.,³² risk factors for recurrence of an ulcer on the plantar surface of the foot (yellow) include the presence of a preulcerative lesion, low day-to-day variation in step activity, and a long cumulative duration of previous foot ulcers; risk factors for recurrence of a pressure-related plantar ulcer (green) include the presence of a preulcerative lesion, lack of both in-shoe peak pressure below 200 kPa and therapeutic-footwear adherence higher than 80%, high barefoot dynamic peak plantar pressure, and low day-to-day variation in step activity.



Engl J Med 2017;376:2367-75.
OI: 10.1056/NEJMra1615439
Copyright © 2017 Massachusetts Medical Society.



Affinché la lesione neuropatica possa guarire, è necessario evitare il conflitto tra la calzatura e la pianta del piede.

Pertanto, nelle lesioni plantari neuropatiche, è assolutamente necessario consigliare al paziente di non deambulare fino a quando non si procurerà un tutore di scarico specifico.

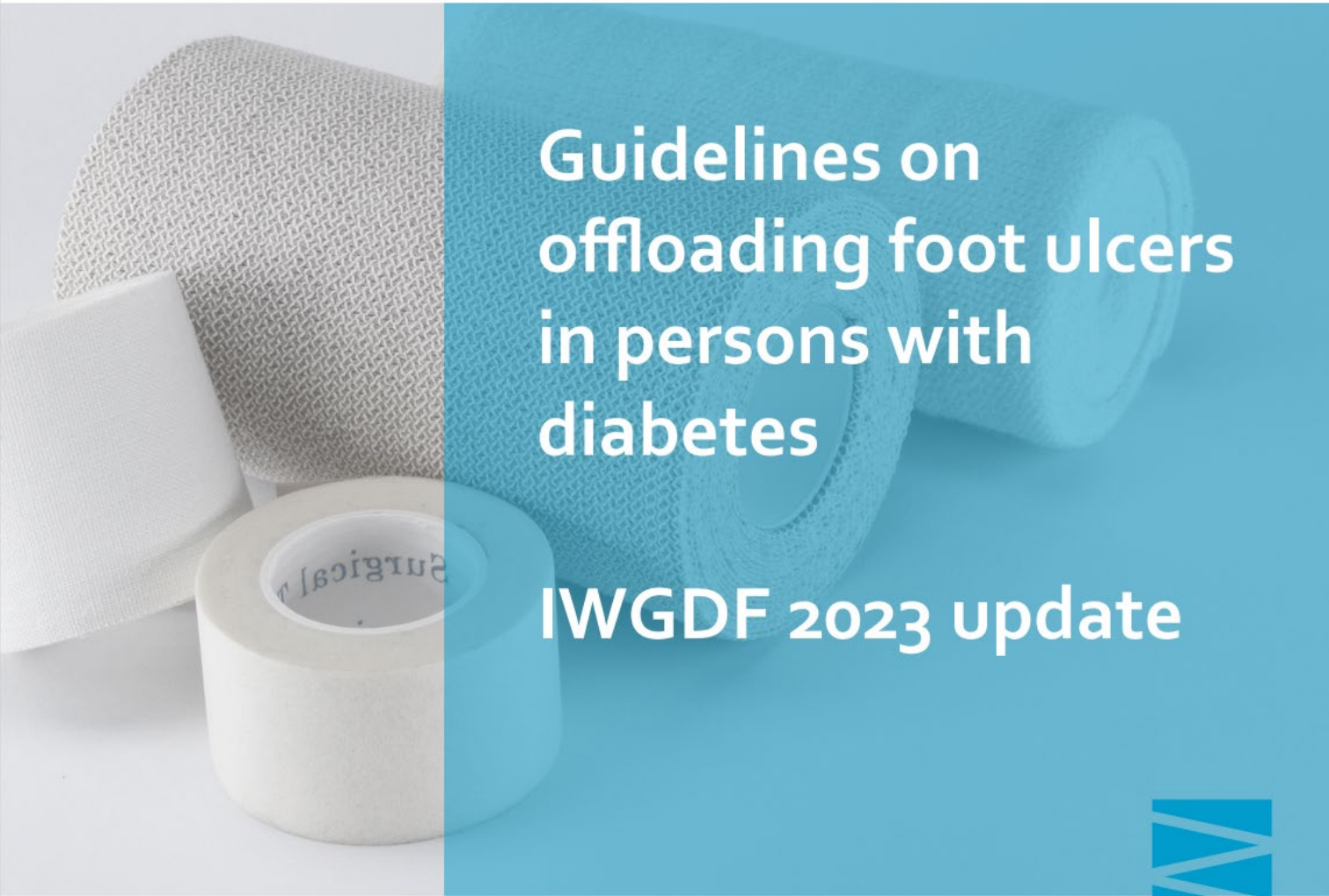
**Documento di Consenso
Internazionale sul Piede Diabetico**

Seconda Edizione Italiana

Gruppo di Studio Internazionale Piede Diabetico

*Gruppo di Studio Interassociativo Piede Diabetico
della Società Italiana di Diabetologia e
della Associazione Medici Diabetologi*





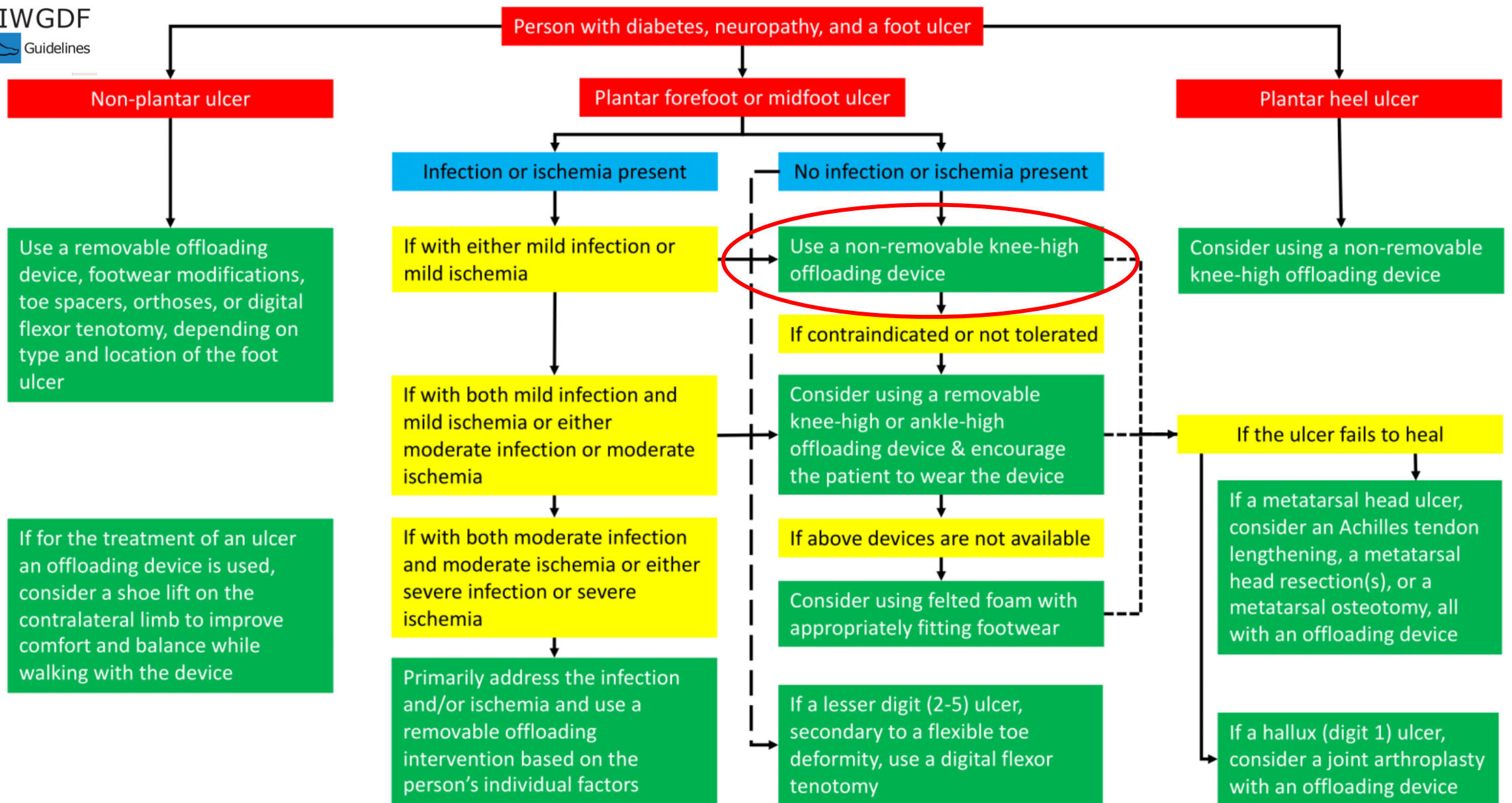
Guidelines on offloading foot ulcers in persons with diabetes

IWGDF 2023 update





*«Per la guarigione di un'ulcera
neuropatica dell'avampiede o del
mesopiede in una persona con
diabete, raccomandiamo l'utilizzo
di un dispositivo di scarico al
ginocchio non rimovibile come
prima scelta per il trattamento di
scarico...»*



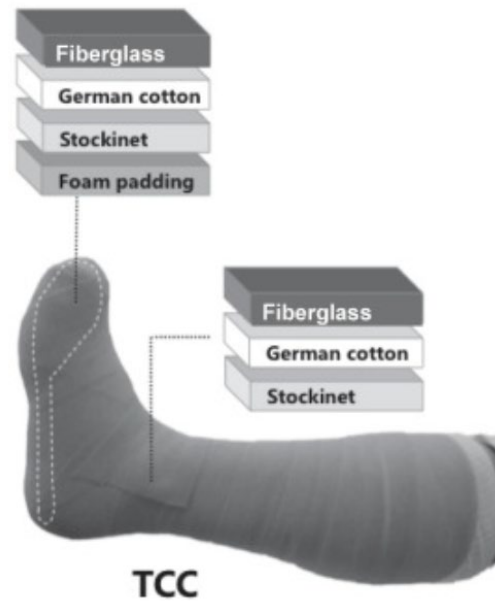
RACCOMANDAZIONE I

- I a. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, use a non-removable knee-high offloading device as the first choice of offloading treatment to promote healing of the ulcer. (GRADE recommendation: Strong; Certainty of evidence: Moderate)
- I b. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for which a non-removable knee-high offloading device is to be used, choose either a total contact cast or non-removable knee-high walker based upon local resources and the person's individual factors and acceptability. (Conditional; Moderate)

Il **GOLD STANDARD** è il
dispositivo di scarico al
ginocchio **non rimovibile**



COS'È IL TOTAL CONTACT CAST?



The total contact cast (TCC) is a useful treatment to offload neuropathic foot ulcers. The classical TCC is applied with the patient lying in a supine position, using minimal undercast padding with added protection at the bony prominences followed by a top layer of Plaster of Paris. The TCC has been modified such that it is a semi-rigid boot made of a synthetic casting tape that has cotton wool and semi-compressed felt applied under it, with the foot being cast at a 90° angle to the leg. It is applied from the tip of the toes to the tibial tuberosity. The plantar pressure is evenly distributed through the sole of the foot and also transferred to the lower leg by covering a large surface area of the foot and leg with casting tape.

Effectiveness of offloading interventions to heal foot ulcers in persons with diabetes: a systematic review

[Peter A. Lazzarini](#),^{1,2} [Gustav Jarl](#),^{3,4} [Catherine Gooday](#),^{5,6} [Vijay Viswanathan](#),⁷ [Carlo F. Caravaggi](#),^{8,9}
[David G. Armstrong](#),¹⁰ and [Sicco A. Bus](#)¹¹

PICO b In people with a plantar DFU, are TCCs compared with other non-removable knee-high offloading devices effective to heal the DFU?

Summary of the evidence.

primarily reported on pa
recent meta-analysis¹² in
included in the older me
not included in either m

The meta-analysis by He
of bias^{19,60,62}) with a cur
to achieve healing betwe
0.14; $P = .82$).¹² The add
TCC, non-removable wal
non-removable walker fo
days; $P = .767$)³⁶.

Evidence statement. TCC
neuropathic plantar fore

QoE. Moderate: Based on
low risk of bias—and an
none of the RCTs was po

References. Health Quali

[Ont Health Technol Assess Ser.](#) 2017; 17(12): 1–124.

Published online 2017 Sep 21.

PMCID: PMC5628703

PMID: [28989556](#)

Fibreglass Total Contact Casting, Removable Cast Walkers, and Irremovable Cast Walkers to Treat Diabetic Neuropathic Foot Ulcers: A Health Technology Assessment

CONCLUSIONS

[Go to:](#) ►

The clinical evidence suggests that fibreglass total contact casting, removable cast walkers, and irremovable cast walkers are beneficial in the treatment of neuropathic, noninfected foot ulcers in patients with diabetes but without severe peripheral arterial disease. Compared to removable cast walkers, ulcer healing was improved with total contact casting (moderate quality evidence; risk difference 0.17 [95% confidence interval: 0.00–0.33]) and irremovable cast walkers (low quality evidence; risk difference 0.21 [95% confidence interval 0.01–0.40]). Irremovable cast walkers were as effective as total contact casting for treating diabetic foot ulcers and were associated with fewer costs.





Diabetic foot ulcer: Challenges and future

Li Yang, Gui-Chuan Rong, Qi-Nan Wu

Total Contact Cast



- Riduce la pressione sull'ulcera dell'84%-92%.
- È efficace per la maggior parte delle ulcere plantari diabetiche non ischemiche e non infette, con un tasso di guarigione dell'ulcera compreso tra il 69,6% e il 73,9%.
- Può ridurre l'infiammazione locale, contribuire a ridurre l'edema durante la guarigione delle ferite, accelerare la guarigione dell'ulcera e proteggere il piede dalle infezioni.



- Controindicato in caso di infezione e di ischemia.
- Non è facile da smontare e il suo utilizzo limita le attività quotidiane.
- L'uso di supporti inappropriati può causare irritazione, ulcerazione e infezione della pelle, e l'uso prolungato può causare debolezza muscolare.
- Richiede la collaborazione di medici esperti, tecnici e pazienti.

Review

Knee-High Devices Are Gold in Closing the Foot Ulcer Gap: A Review of Offloading Treatments to Heal Diabetic Foot Ulcers

Peter A. Lazzarini ^{1,2,*}  and Gustav Jarl ^{3,4} 

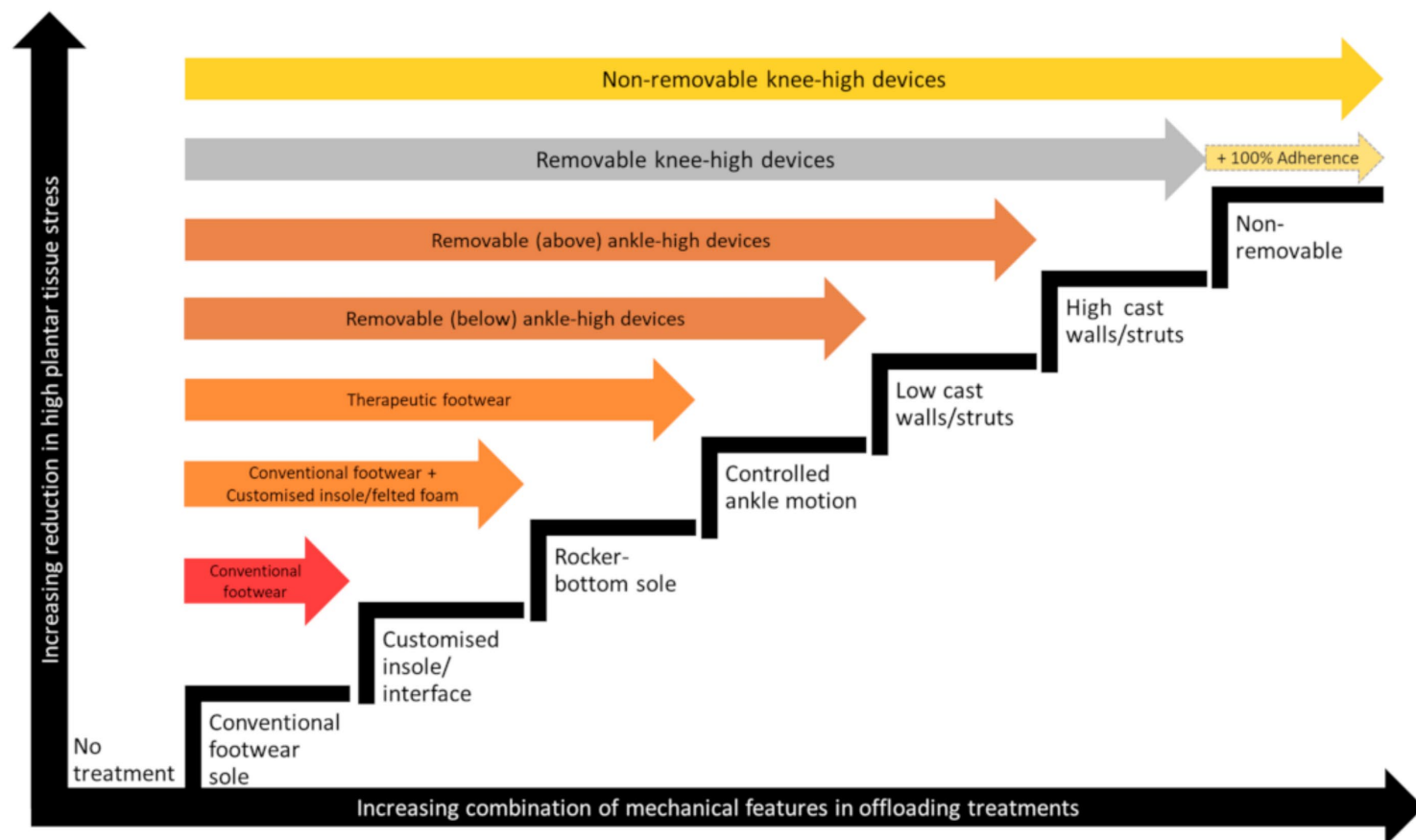
Medicina 2021, 57, 941. <https://doi.org/10.3390/medicina57090941>

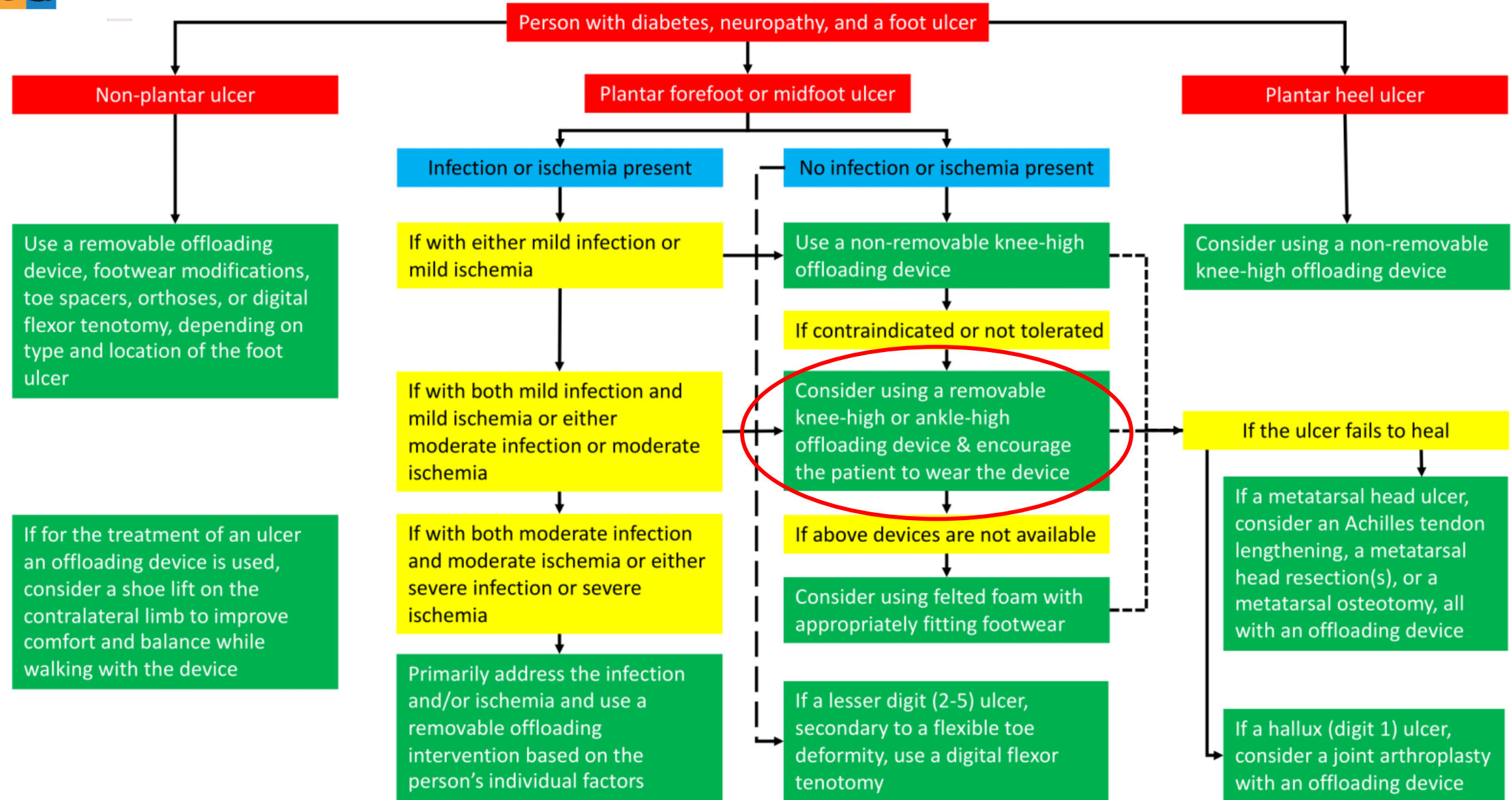
<https://www.mdpi.com/journal/medicina>

Reducing high plantar tissue stress is critical to healing DFU.

Highquality evidence demonstrates that knee-high devices, always adhered to, are the gold standard offloading treatment to reduce high plantar tissues stress and more effectively heal DFU.

However, studies also show these knee-high devices are somewhat **rarely prescribed** in clinical practice, and when they are, patients have low acceptance or adherence to using these best practice treatments.





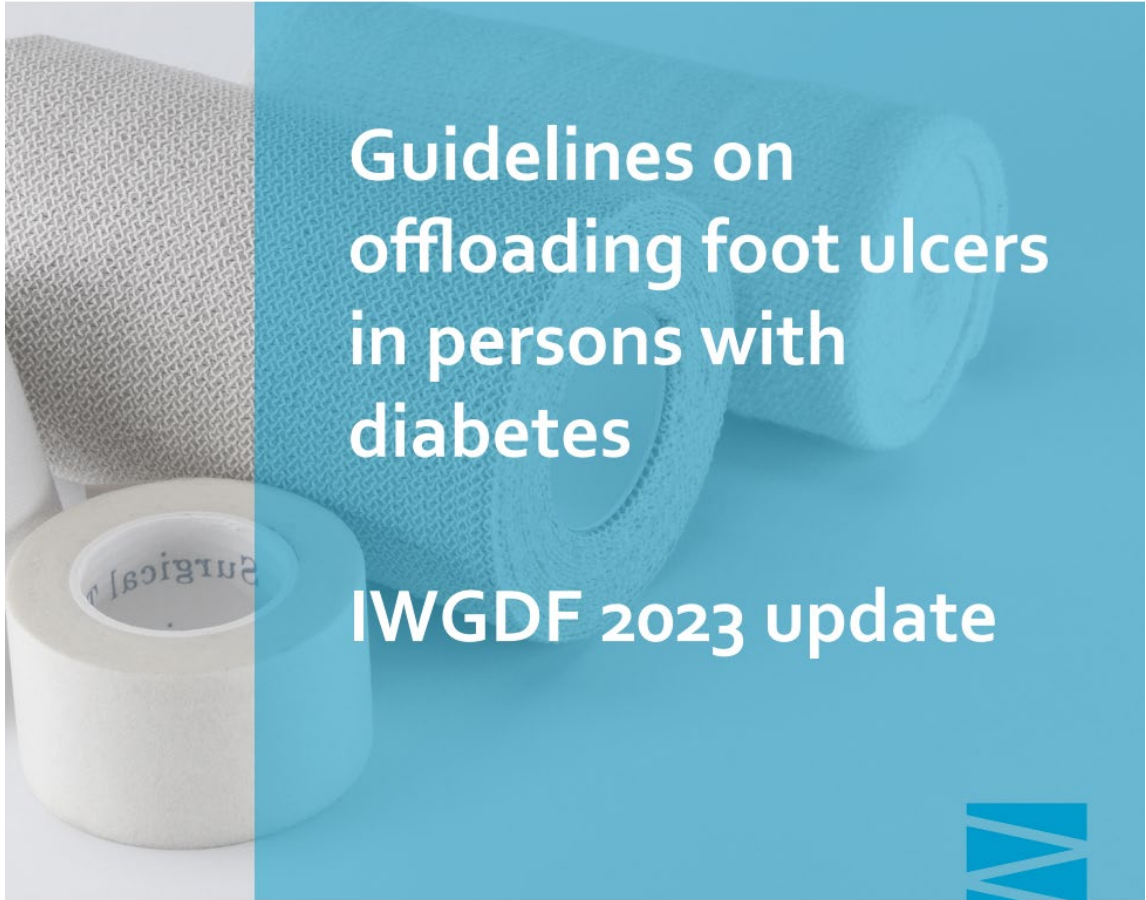
2. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for whom a non-removable knee-high offloading device is contraindicated or not tolerated, consider using either a removable knee-high or ankle-high offloading device as the second choice of offloading treatment to promote healing of the ulcer, and encourage the person to use the device during all weight-bearing activities. (Conditional; Low)

E SE IL
PAZIENTE NON
TOLLERA IL
DISPOSITIVO
NON
RIMOVIBILE?



IWGDF 2023 VS 2019: QUALI DIFFERENZE NELLA PRATICA?

I dispositivi di scarico rimovibili alti al ginocchio e alla caviglia sono ora raggruppati in un'unica raccomandazione come dispositivo di scarico di seconda scelta, dopo il tutore di scarico alto al ginocchio non rimovibile



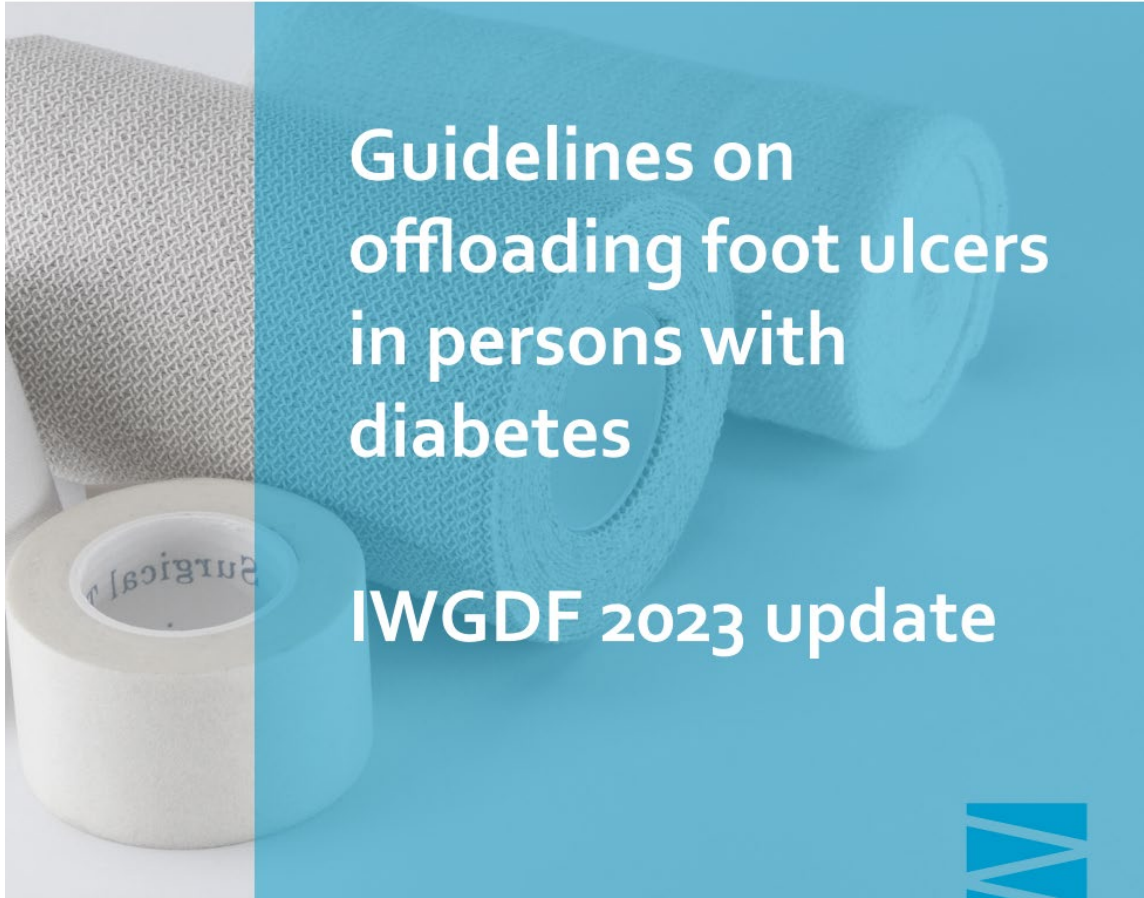
Guidelines on
offloading foot ulcers
in persons with
diabetes

IWGDF 2023 update



IWGDF 2023 VS 2019: QUALI DIFFERENZE NELLA PRATICA?

Sono stati aggiunti nuovi importanti outcomes, come la persistenza della guarigione, l'equilibrio e l'insorgenza di eventi/effetti avversi che possono favorire nuove lesioni, cadute, infezioni o amputazioni



Guidelines on
offloading foot ulcers
in persons with
diabetes

IWGDF 2023 update

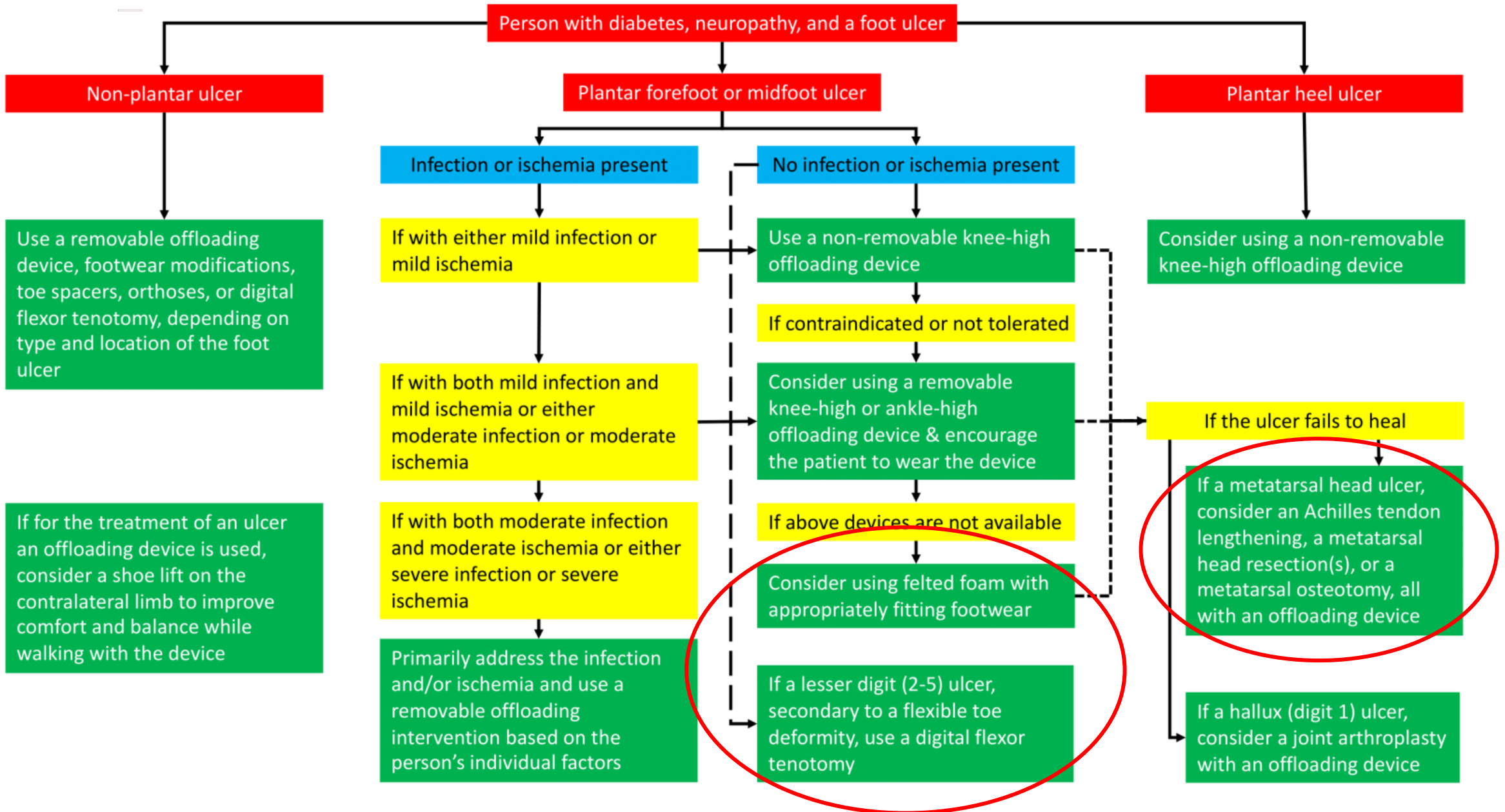


IWGDF 2023 VS 2019: QUALI DIFFERENZE NELLA PRATICA?

Le persone con una DFU con dispositivo di scarico all'altezza del ginocchio o della caviglia possono presentare problemi di equilibrio o disturbi posturali con perdita di stabilità se vi è una significativa differenza di spessore tra le calzature dei due piedi, con differente lunghezza tra una gamba e l'altra.



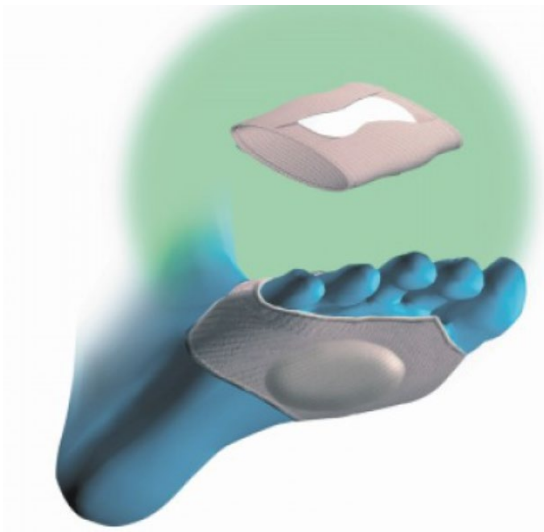




IWGDF Offloading Guideline



3. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer, do not use, and educate the person not to use conventional footwear or standard therapeutic footwear over an offloading device, to promote healing of the ulcer. (Strong; Low)
4. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer for which offloading devices are not available, consider using felted foam in combination with appropriately fitting footwear as the third choice of offloading treatment to promote healing of the ulcer. (Conditional; Very Low)





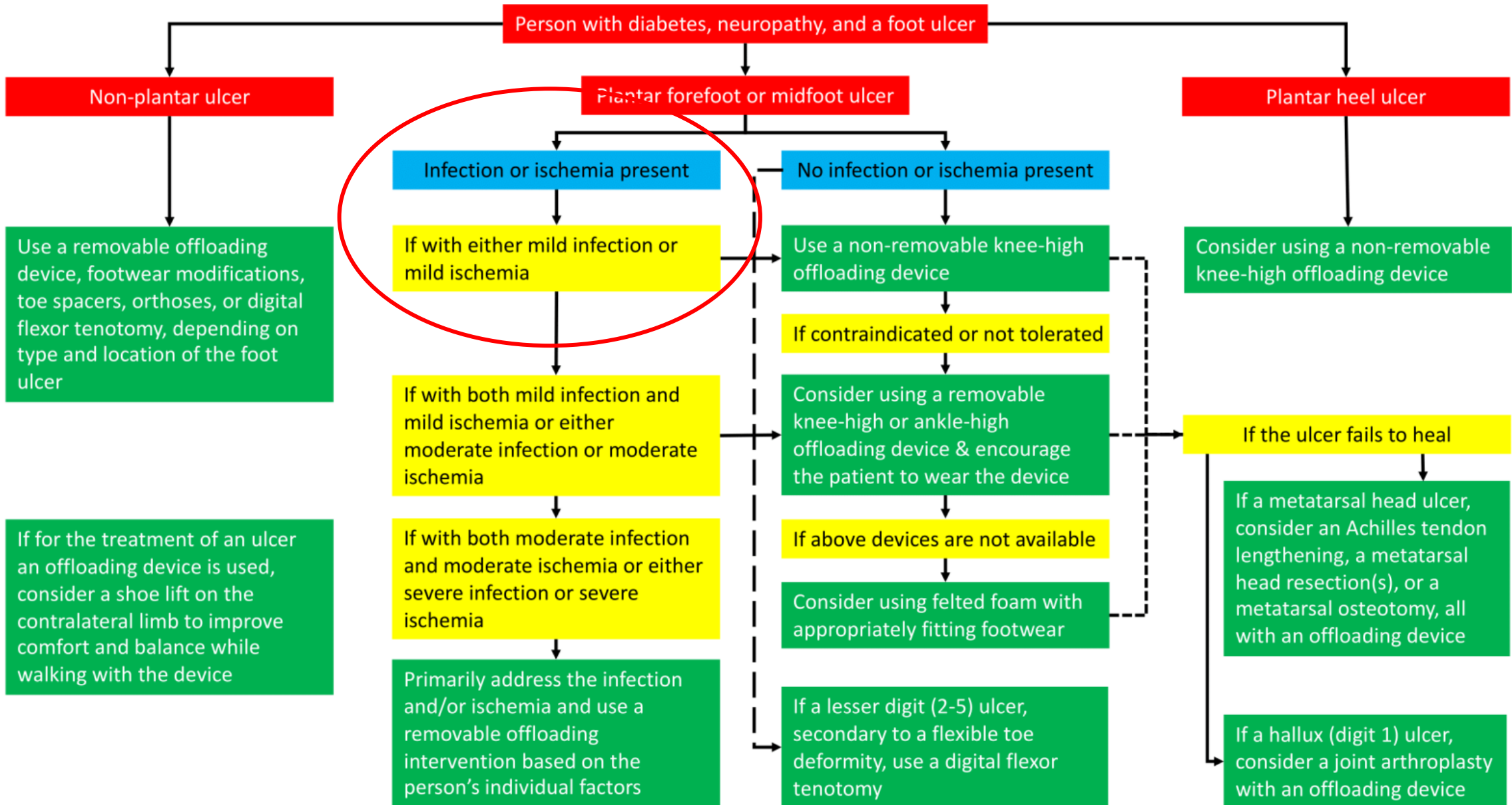
«Se lo scarico non chirurgico fallisce, si consiglia di prendere in considerazione interventi di scarico chirurgico per la guarigione delle teste metatarsali e delle ulcere digitali»

IWGDF Offloading Guideline



- 5a. In a person with diabetes and a neuropathic plantar metatarsal head ulcer for which non-surgical offloading treatment fails, consider using Achilles tendon lengthening in combination with an offloading device to promote and sustain healing of the ulcer. (Conditional; Moderate)
- 5b. In a person with diabetes and a neuropathic plantar metatarsal head ulcer for which non-surgical offloading treatment fails, consider using metatarsal head resection in combination with an offloading device to promote and sustain healing of the ulcer. (Conditional; Low)
- 5c. In a person with diabetes and a neuropathic hallux ulcer for which non-surgical offloading treatment fails, consider using joint arthroplasty in combination with an offloading device to promote and sustain healing of the ulcer. (Conditional; Low)
- 5d. In a person with diabetes and a neuropathic plantar ulcer on metatarsal heads 2-5 for which non-surgical offloading treatment fails, consider using a metatarsal osteotomy in combination with an offloading device to promote and sustain healing of the ulcer. (Conditional; Very low)
- 6. In a person with diabetes and a neuropathic plantar or apex ulcer on digits 2-5, secondary to a flexible toe deformity, use a digital flexor tenotomy to promote and sustain healing of the ulcer. (Strong; Moderate)





IWGDF Offloading Guideline



E SE LA
LESIONE È
ISCHEMICA
E/O INFETTA?

7. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischaemia, consider using a non-removable knee-high offloading device to promote healing of the ulcer. (Conditional; Low)
8. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both mild infection and mild ischaemia, or with either moderate infection or moderate ischaemia, consider using a removable offloading device to promote healing of the ulcer. (Conditional; Low)
9. In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with both moderate infection and moderate ischaemia, or with either severe infection or severe ischaemia, primarily address the infection and/or ischaemia, and use a removable offloading intervention over no offloading based on the person's individual factors, to promote healing of the ulcer. (Strong; Very low)



E SE LA LESIONE NON È DELL'AVAMPIEDE/MESOPIEDE?

10. In a person with diabetes and a neuropathic plantar rearfoot ulcer, consider using a non-removable knee-high offloading device over a removable offloading device to promote healing of the ulcer. (Conditional; Very low)
11. In a person with diabetes and a non-plantar foot ulcer, use a removable offloading device, footwear modifications, toe spacers, orthoses, or digital flexor tenotomy, depending on the type and location of the foot ulcer, to promote healing of the ulcer. (Strong; Very low)



ESISTONO ANCHE DISPOSITIVI DA UTILIZZARE NEI PAZIENTI ALLETTATI

Tutori in schiuma per:

- lo scarico del calcagno durante il decubito o nelle fasi post operatorie di tallone o avampiede;
- La gestione della ferita post amputazione dell'avampiede;
- La gestione delle fasi post operatorie al tendine.



DA COSA DIPENDE LA COMPLIANCE?

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 ^{a,c}

“Most quantitative papers (70%) defined adherence as the percentage of offloading time calculated from 15 to 16 h a day. The other 30% of the studies defined adherence as the daily steps taken with the shoe/device.”

Biological and psychosocial factors.

Factors		Factors contributing to adherence	Factors contributing to non-adherence
Biological factors	Age	More advanced years [32,33]	Younger & older age [40]
	Gender	Men [30]	Women less satisfied with shoe price [36], shoe exterior [21,35], shoe characteristics [35], affected by self-image [22], unwilling to wear it in public [36,38].
	Diabetes type and duration	T1DM [32]; T2DM [33] Longer duration [32]	T2DM [32]; T1DM [33] Longer & shorter duration [40]
	BMI and general health	Lower body weight [31] Having good health [36] or having replacement therapy less frequently [33].	Overweight or obese [31] Having poor health [36], or having renal replacement therapy more frequently [33]
	Foot complications and discomfort	Having more severe neuropathy and foot pain [29]	N/A
		Having more severe foot deformity [21,31,32]	N/A
		N/A	Presence of foot complications of all severity levels [40]
		A previous DFU [21,36,37], an active DFU [29,37], no active DFU [39]	N/A
		Having amputations [21,32,33,36,37]	N/A
		N/A	Experienced foot complications caused by footwear [16]
		N/A	Pain, immobility [20] and altered posture [16,20,29] when using offloading

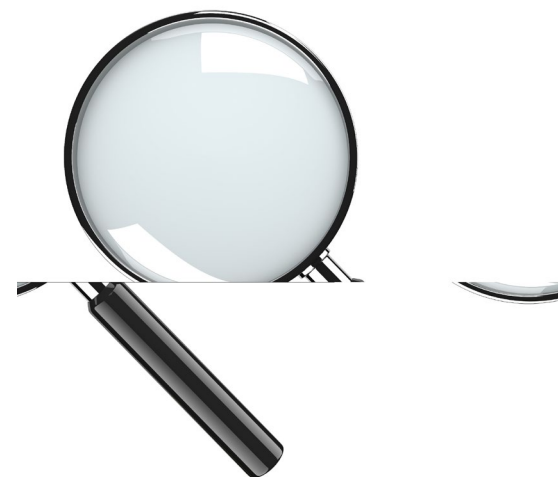
Psychosocial factors	Factors	Factors contributing to adherence	Factors contributing to non-adherence
	Education, employment, price and culture	A minimum level of education [32] Paying jobs [36,37] Offloading is reasonably priced [36] N/A	A higher level of education [32] Retired or unemployed [36,37] Offloading is expensive [42] Offloading can be shameful (is stigmatizing) in African and Latin American cultures [42]
	Social and healthcare support	Free care [36] Happy with healthcare services [37]	Paid care [16] N/A
	Limitation of daily activities	N/A	Offloading impedes driving, walking stairs, gardening, attending social occasions, shopping, returning to work [16,20,22]
	Emotional	Highly independent [37] N/A N/A N/A N/A N/A N/A	Reliant on others for care (family members) [16] Unwillingness to wear it [16,30] Offloading is too complex and burdensome [16] Feeling ashamed to wear it [20,21] Feeling degraded by offloading [42] Experienced shock and distress [20] Having a negative body image [22]
	Perceptions	Wanting to look functionally normal [22] Understanding the benefit of wearing offloading [32,37] Having a positive attitude on shoe aesthetic [31,33,36]; N/A Wearing low height shoes [32] Wearing semi-customized [32] N/A N/A N/A N/A N/A	N/A Not seeing any benefits of offloading [20] Being unhappy with shoe aesthetics [20–22,32,35,38,40,42] (Shoes were: not fashionable [38], ugly/not elegant [21], unattractive [20]) Shoes are heavy [20,21,32,40] Using higher shoes [32,43] Using fully customized shoes [32] Being dissatisfied with the fabric [20,21] Shoes deteriorate fast [21,38] Shoes are uncomfortable [20,21,32,38,40] Own shoes preferred [38] Aware that the foot is at a high severity level [40]
	Beliefs	Having a strong sense of control over own situation/condition [36] N/A N/A Offloading can enhance mobility [20,22] and helps to resume work [20] Thoughts that neuropathy increases chances of DFU [37,42] Beliefs that DFU is already severe [33] N/A	Beliefs of having no control over a DFD [20] Thinking that offloading is not needed [20], or it is not needed indoors/at home [16,22,40] Beliefs that there are no risks indoors [22] N/A
	Knowledge	N/A Knowing that DFU is recurrent [33] Knowing that offloading protects the feet [21,32] Knowing that offloading can help avoiding [20,21,36,40] or healing [20,36,37] DFU. N/A	N/A Having limited knowledge on offloading benefits [16,20], its functions, or daily use [20]. N/A
	Behavior	Increasing the number of daily steps [31] Being consistent with foot care [34] Following the doctor's recommendation [33] Placing the footwear at hand [37]	Knowing that footwear is important for DFU [40] Walking a constant number of steps [31] N/A N/A Placing the footwear out of sight [37]

CONCLUSION:

“Offloading treatment is the core of diabetic foot management, and enhanced adherence to foot offloading is therefore crucial in preventing and in treating diabetic foot disease. Furthermore, offloading reduces DFU healing time, re-ulceration, amputations, and **saves lives.**”

TAKE-HOME MESSAGES

- L'offloading del piede diabetico è un componente essenziale nella gestione delle ulcere plantari, poiché aiuta a promuovere la guarigione e a prevenire le complicazioni.
- Riuscire a caratterizzare la tipologia di lesione precocemente permette di mettere in atto la strategia terapeutica più appropriata.
- È importante istruire il paziente al corretto utilizzo dei tutori di scarico ed educarlo al suo utilizzo e istruirlo su quanto la compliance sia determinante per la guarigione.



«Perché un'ulcera neuropatica ben scaricata deve guarire»



A photograph of the Policlinico hospital building, a large, multi-story structure with a classical facade featuring columns and arched windows. A large, dark green sign with gold lettering reads "POLICLINICO" across the top of the building. The image is framed by a white, hand-drawn border.

POLICLINICO

Grazie dell'attenzione
