

ASSESSMENTS AND SUMMARY OF JUDGEMENTS TABLES FOR ALL CLINICAL QUESTIONS IN THE OFFLOADING GUIDELINE

CLINICAL QUESTION 1

In a person with diabetes and a plantar forefoot or midfoot ulcer, should non-removable offloading devices be used over removable offloading devices?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Non-removable offloading devices
COMPARISON:	Removable offloading devices
MAIN OUTCOMES:	Healed ulcers (at 3 months); Plantar pressure (with treatment); Weight-bearing activity (daily steps); (Non-)Adherence to treatment (self-reported non-adherence); Adverse effects (of new ulcers or lesions); Adverse effects (of falls); Adverse events (of infection); Adverse events (of amputation); Quality of life (patient satisfaction with offloading intervention); Costs (one-off material costs for initial treatment); Costs (cost-effectiveness over the treatment period); Balance
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects How substantial are the desirable anticipated effects?		

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	Based on aggregated small-to-moderate desirable effects found in favour of non-removable offloading devices in the meta-analyses on the primary (critical outcome) of increased healed ulcers (relative risk (RR) (95% CI) 1.25 (1.10 to 1.43) in 14 trials) and for the additional (critical) outcomes of reduced infections (0.55 (0.30 to 1.00) in 6 trials), and reduced amputations (0.53 (0.19 to 1.50) in 3 trials). Further, these desirable effects are augmented by lower quality evidence for moderate desirable effects on adherence, weight-bearing activity, costs and cost-effectiveness and no difference in falls.	Although studies that reported the incidence of falls found no difference in falls incidence- one retrospective study comparing TCC with removable devices noted two patients with bilateral TCC discontinued the intervention because of falls, without any similar discontinuances in the removable offloading group.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	Based on aggregated trivial-to-small undesirable effects found against non-removable offloading devices in the meta-analyses for the additional (critical) outcome of increased new ulcers/lesions (RR 1.50 (0.81 to 2.80) in 12 trials), increased peak pressure in 5 trials and reduced patient satisfaction in 2 trials.	<p>Multiple review papers have referenced TCC as being contraindicated for people with balance problems, however, evidence to support this recommendation is lacking.</p> <p>In consideration of plantar pressure outcomes, it is important to note the comparisons that were made. The comparisons that suggested removable devices may provide greater offloading were between TCC and removable knee-high cast walkers that could be converted to a non-removable form</p>

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input checked="" type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	Although the average certainty of evidence across all 9 outcomes would be considered low, an overall certainty of evidence of moderate was assigned in association the primary outcome of healing having moderate certainty of evidence.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input checked="" type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	Based on our above assessments of moderate desirable effects outweighing the small undesirable effects.	

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input checked="" type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	Based on 4 trials reporting a small non-significant increase of a mean €14.6 for the initial one-off material costs for non-removable offloading devices compared to removable devices.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	Based on our systematic review assessment that there was a low certainty of evidence for the (one-off material) costs outcome.	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	<p>Based on the one cost-effectiveness analysis rated at low risk of bias finding moderate cost-effectiveness in favour of non-removable offloading devices.</p>	
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Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this intervention does not appear to promote equity of healthcare. 1. Likely to only be available to those with the ability to pay for the non-removable offloading devices. 2. Likely to only be available to those who have access to clinicians with the skills and resources to provide non-removable offloading devices. 3. Likely to be unavailable to those living in geographically disadvantaged locations, e.g. developing countries</p>	

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on multiple published surveys of clinical practice, acceptability to using non-removable offloading devices is low.</p>	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>In some countries the traditional TCC is probably not feasible to introduce into the healthcare system, due to the lack of availability of the equipment and skilled clinicians required to implement its use. However, in the context of this question that is comparing non-removable devices to other removable devices, most removable devices could readily be converted to a non-removable format using cast tape, straps or other methods.</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ●
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CONCLUSIONS

Recommendation

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; CoE: Moderate).

Voting: Unanimous for the direction of the recommendation. The decision for a strong recommendation was not unanimous, with the majority of members of the group voting for a strong recommendation and a minority of member(s) of the group voting for a conditional recommendation.

Justification

Knee-high non-removable devices are recommended as the first choice for offloading plantar forefoot or midfoot diabetes related foot ulcers as evidence to date indicates their use results in improved healing outcomes and reduced amputations. Additionally, there is some evidence that they are more cost effective than removable offloading devices. The improved healing noted with non-removable devices seems counterintuitive to the finding that some removable devices yield equivalent or greater reductions in plantar pressure than non-removable devices. However, these seemingly contradictory findings are explained by the defining feature of non-removable devices. Unless a patient that has been provided a non-removable device returns to their care provider without the device in use, it is generally assumed the patient has been fully adherent in donning the device at all times. In contrast, objective monitoring of adherence to removable devices has demonstrated patients often engage in weight bearing activity without the use of their offloading devices. Additional benefits noted in association with non-removable devices included reduced infections and amputations, as well as improved cost-effectiveness.

Admittedly, there are some potential drawbacks associated with non-removable knee-high offloading devices beyond them not demonstrating the highest possible reduction in plantar pressure. There is an increased risk of secondary ulcer formation in association with the use of non-removable devices. There are also challenges with patient acceptability of such interventions. Also of note is a perceived concern regarding health equity. Our expert opinion is that health equity is likely diminished in consideration of the use of non-removable devices, as their use is likely limited by patients' ability to pay for them and patients' access to clinicians with the skills and resources to provide the interventions.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 2

In a person with diabetes and a plantar forefoot or midfoot ulcer, should a total contact cast be used over another non-removable knee-high offloading device?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Total contact casts
COMPARISON:	Non-removable knee-high offloading devices
MAIN OUTCOMES:	Healed ulcer (at 3 months); Plantar pressure (with treatment); Weight-bearing activity (daily steps); Adherence; Adverse effects (of new ulcers or lesions); Adverse effects (of falls); Adverse events (of infections); Adverse events (of amputations); Quality of life (patient satisfaction with offloading intervention); Costs (one-off material costs for initial treatment); Cost (cost-effectiveness over the treatment period); Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	Based on aggregated small difference in desirable effects between TCCs and non-removable offloading devices (iTCCs) in the meta-analysis on the primary (critical outcome) of increased healed ulcers (relative risk (RR) (95% CI) 1.05 (0.92 to 1.19) in 4 trials) which was rated as demonstrating moderate certainty of evidence.	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on aggregated small undesirable effects found against TCCs in the meta-analyses for the additional (critical) outcome of increased adverse events for new ulcers/lesions (RR 2.04 (0.70 to 5.96) in 5 trials), quality of life (rated as patient satisfaction) in favour of iTCCs, smaller reductions in plantar pressure with TCC (55.9kPa; 95% CI 27.9 to 83.8) in 1 RCT of low risk of bias and 4 other observations studies, and otherwise similar adverse events for infections, amputations and falls.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input checked="" type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>Based on our assessment of the certainty of evidence for the primary (critical outcome) of healed ulcers and plantar pressure reductions from our systematic review of the literature, along with mostly low certainty of evidence for all other additional outcomes.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input checked="" type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on our above assessments of small desirable effects based on moderate certainty of evidence and small undesirable effects based on moderate to low certainty of evidence, we do not consider either intervention to be favoured.</p>	

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input checked="" type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	Based on 4 trials, with 2 showing one-off costs favoured the TCCs and the other 2 favouring iTCCs.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	Based on 4 trials with serious inconsistency, indirectness and imprecision.	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input checked="" type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	Based on 1 large cost-effectiveness analysis (Health Quality Ontario 2017), evidence from several trials and expert opinion which consistently showed that iTCCs were more cost-effective than TCCs over 3 different economic outcomes (costs per patient for 3 months treatment, costs per patient for 6 months treatment, and costs and healing probabilities over 1,000 diabetes-related foot ulcer patients) and rated as having moderate certainty of evidence	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this TCC intervention is likely to reduce equity when compared to an iTCC control as TCCs are: 1. Likely to only be available to those with the ability to pay for ongoing TCC materials (rather than one-off cost for iTCCs). 2. Likely to only be available to those who have access to clinicians with the skills and resources to provide TCCs (whereas iTCCs require less skills and resources). 3. TCC intervention may require more frequent clinic visits which may be a hardship on patients</p>	
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Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on multiple published surveys of clinical practice, patient acceptability for TCCs is low and lower than that of iTCCs. Clinicians' concerns over possibility of adverse events are likely partially responsible for limited use of TCC.</p>	

Feasibility
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>In most countries this intervention is probably not feasible to introduce into the healthcare system, due to the lack of skilled clinicians required to implement TCCs, as opposed to iTCCs, plus these devices have not been routinely implemented even in high-income countries.</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ●	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the strength of the recommendation. The decision for the direction of the recommendation was not unanimous, with the majority of members of the group voting for a conditional recommendation for either the intervention or the comparison and a minority of member(s) of the group voting for a conditional recommendation against the intervention.

Justification

Similar clinical outcomes are likely to be achieved with either a total contact cast or non-removable knee-high cast walker, however, non-removable knee-high devices have been shown to provide greater offloading of plantar pressure. Implementation of the use of non-removable cast walkers is likely easier as cost effectiveness, equity, acceptability and feasibility factors tend to favour non-removable cast factors. The offloading choice should ultimately be dependent upon the resources available, technician skills, patient preferences, and the extent of foot deformity present (i.e. using a total contact cast with a severely deformed foot).

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 3

In a person with diabetes and a plantar forefoot or midfoot ulcer, should removable knee-high offloading devices be used over removable ankle-high offloading devices?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Removable knee-high offloading devices
COMPARISON:	Removable ankle-high offloading devices
MAIN OUTCOMES:	Healed ulcer (at 3 months); Plantar pressure (with treatment); Weight-bearing activity (daily steps); (Non-)Adherence to treatment (self-reported non-adherence); Adverse effects (of new ulcers or lesions); Adverse effects (of falls); Adverse events (of infections); Adverse events (of amputations); Quality of life (patient satisfaction with offloading interventions); Costs (one-off material costs); Costs (cost-effectiveness over the treatment period); Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large	Small-to-moderate desirable effects for the intervention knee-high offloading devices compared to ankle-high on weight-bearing activity reductions (MD -968 daily steps (-2,003, 67),) and on plantar pressure reductions from 1 RCT of low risk of bias and 6 other observations studies. Trivial or small	

<ul style="list-style-type: none"> ○ Varies ○ Don't know 	<p>difference for adverse events (new ulcers, Infection, and falls between the two types of devices. We find the overall desirable effects to be small.</p>	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large ○ Moderate ● Small ○ Trivial ○ Varies ○ Don't know 	<p>Little-to-no difference in desirable effects in favour of the comparator ankle -high offloading devices in the meta-analysis on the primary (critical outcome) of increased number of healed ulcers RR 1.00, 95% CI 0.86-1.16). Furthermore, based on aggregated trivial-to-small undesirable effects found against removable knee-high offloading devices in the meta-analyses for the additional (critical) outcome of reduced adherence (RR 0.86 (0.74 to 1.00)), plus, potentially adverse events for amputations (1.96 (0.52, 7.34) and costs, we find the overall undesirable effects to be small.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>Based on our assessment of low certainty of evidence for the primary (critical outcome) of healed ulcers and plantar pressure reductions from our systematic review of the literature, along with (very) low to moderate certainty of evidence for all other additional outcomes, we find the overall certainty of evidence to be very low.</p>	<p>Because some outcomes favour ankle high and some favour knee high</p>

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ● No important uncertainty or variability 	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input checked="" type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on our above assessments of small desirable effects and moderate undesirable effects based on low certainty of evidence.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input checked="" type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Ankle high devices are generally less expensive however the level of evidence is low.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>Based on 1 trial with serious risk of bias and very serious imprecision.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input checked="" type="radio"/> Varies <input type="radio"/> No included studies 	<p>Based on 1 large cost-effectiveness analysis (Health Quality Ontario 2017), based on evidence from several trials and expert opinion, consistently showed that removable knee-high devices were more cost-effective than therapeutic footwear over 3 different economic outcomes that we consider similar in functionality and costs to removable ankle high devices. However, based on this systematic review, ankle-high devices were found to be superior to knee-high devices uncertainty remains around the cost-effectiveness of the devices. The variety of different type of devices included in the b the intervention and comparator group increases the uncertainty around the cost effectiveness of individual devices.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input type="radio"/> Probably reduced <input checked="" type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, the removable knee-high devices likely has a similar effect on equity to removable ankle-high devices as they are both equally: 1. Likely available to those of lower socio-economic status in terms of costs. 2. Likely available as clinicians require very little skills and resources to provide these devices. and 3. Likely equally available or unavailable to those living in geographically disadvantaged locations, e.g. developing countries, for the above reasons.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on multiple published surveys of clinical practice, acceptability to using removable knee-high devices is slightly lower than ankle-high devices, plus, our meta-analysis finding that patient adherence is likely slightly reduced in knee-high devices as well.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on our expert opinion, as to our knowledge no evidence exists on feasibility for this comparison, this removable knee-high device is likely to have a similar effect on feasibility to removable ankle-high devices as both are typically purchased for similar costs from similar companies.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ●	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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 wear the device during all weight-bearing activities (Conditional; **Low**).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Our systematic review has found that ankle-high devices are superior to knee-high devices for the primary outcome of number of ulcers healed at three months. However, knee-high devices were associated with a reduction in plantar pressure and weight bearing activity compared to ankle-high devices. This study has shown reduced levels of adherence for wearing knee-high compared to ankle-high devices. The lower levels of adherence could explain why the mechanistic effects of a reduction in plantar pressure and weight bearing activity observed in knee-high devices do not lead to an improvement in ulcer healing rates. There were similar adverse events seen within the two groups. There has been one cost effectiveness study comparing knee-high and ankle-high devices, however the assumptions and conclusion in this cost-effectiveness study are different to the current study. Alongside this, the variety of different devices used in both the intervention and comparator group and the difference in costs makes a definitive assessment of cost effectiveness difficult. Therefore, uncertainty remains over the cost effectiveness of knee-high over ankle-high devices to heal diabetes-related foot ulcers. If people with diabetes-related foot ulcers can be encouraged to wear knee-high devices, then given the observed reduction in plantar pressure this could translate into the same or better ulcer healing rates. Given the low certainty of evidence and balance between the value of the primary and secondary outcomes we have advised that, clinicians should use a person-centred approach to recommending either a knee-high or ankle-high device taking into consideration anticipated adherence levels to wearing the device.

In this study we have made an overall judgement that a reduction in weight bearing activity is beneficial to ulcer healing. We acknowledge that in making this assumption we are not considering individuals risk factors or behavioural choices, which are important for both ulcer healing, and future morbidity and mortality. An ideal device would adequately offload an ulcer for healing while allowing the person to maintain or even increase activity levels to contribute to an improvement in overall cardiovascular health and quality of life.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 4

In a person with diabetes and a plantar forefoot or midfoot ulcer, should removable above ankle-high offloading devices be used over removable below ankle-high offloading devices?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Removable ABOVE ankle-high offloading devices
COMPARISON:	Removable BELOW ankle-high offloading devices
MAIN OUTCOMES:	Healed ulcer (at 3 months); Plantar pressure (with treatment); Weight-bearing activity (daily steps); (Non-)Adherence to treatment (self-reported non-adherence); Adverse effects (of new ulcers or lesions); Adverse effects (of falls); Adverse events (of infections); Adverse events (of amputations); Quality of life (patient satisfaction with offloading interventions); Costs (one-off material costs); Costs (cost-effectiveness over the treatment period); Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large	There is no research reporting the clinical outcomes for above ankle high versus below-ankle high offloading devices.	

<input type="radio"/> Varies <input checked="" type="radio"/> Don't know		
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input checked="" type="radio"/> Don't know	There is no research reporting the clinical outcomes for above ankle high versus below-ankle high offloading devices.	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input checked="" type="radio"/> No included studies	There is no research reporting the clinical outcomes for above ankle high versus below-ankle high offloading devices.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● Don't know 	<p>There is no research reporting the clinical outcomes for above ankle-high versus below-ankle high offloading devices.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ● Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know 	<p>Based on expert opinion small or no difference in the cost between above ankle-high and below ankle-high devices.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ○ Low ○ Moderate ○ High ● No included studies 	<p>No studies.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● No included studies 	<p>Based on our expert opinion, as to our knowledge no evidence exists on the cost effectiveness of above ankle-high devices compared to below ankle-high devices and the variety of different types of devices this question could include we concluded that there will be similar costs for both devices. However, there are no cost effectiveness analysis between removable above ankle-high versus removable below ankle-high devices.</p>	

Equity		
What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input type="radio"/> Probably reduced <input checked="" type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, the removable knee-high devices likely has a similar effect on equity to removable ankle-high devices as they are both equally: 1. Likely available to those of lower socio-economic status in terms of costs. 2. Likely available as clinicians require very little skills and resources to provide these devices. and 3. Likely equally available or unavailable to those living in geographically disadvantaged locations, e.g. developing countries, for the above reasons.</p>	
Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Based on our expert opinion, as to our knowledge no evidence exists on the acceptability for this comparison, above ankle devices maybe less acceptability to people with diabetes-related foot ulcer, as in other studies people report a preference for devices that are lower. We do not expect above ankle-high devices compared to below ankle-high devices to have a difference in acceptability for clinicians.</p>	
Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Based on our expert opinion, as to our knowledge no evidence exists on feasibility for this comparison, removable knee-high device are likely to have a similar effect on feasibility to removable ankle-high devices as both are typically purchased for similar costs from similar companies, and the same level of training is required to apply both devices.</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ●	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

No recommendation made.

Voting: Unanimous for not making a recommendation.

Justification

We have decided not to make a recommendation on the use of above ankle-high devices compared to below ankle-high devices to heal diabetes-related foot ulcers. Our systematic review has shown that there is insufficient evidence to answer this question. There are no studies that compared the clinical outcome of ulcer healing between the two different height devices. One cross sectional repeated measure study in a surrogate population (n=11) assessed the impact of strut height on the off-loading capacity of removable cast walkers. This study found lower peak plantar pressures, for the above ankle-high device compared to the below ankle-high device (Crews 2012). Further research is needed to assess whether the superiority in peak pressure reduction observed in the above ankle-high devices translates into improved clinical outcomes for ulcer healing.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 5

In a person with diabetes and a plantar forefoot or midfoot ulcer, should conventional or standard therapeutic footwear be used over offloading devices?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Therapeutic footwear
COMPARISON:	Offloading devices
MAIN OUTCOMES:	Healed ulcers; Plantar pressure; Weight-bearing activity; Adherence; Adverse effects (on new ulcers or lesions); Adverse effects (on falls); Adverse events (on infections); Adverse events (on amputations); Quality of life (patient satisfaction with offloading intervention); Costs (one-off material costs); Costs (cost-effectiveness analyses over the treatment period); Balance;
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large	We judged the overall desirable effects in favour of therapeutic footwear versus offloading devices as small, based on that offloading devices may increase new ulcers or lesions.	

<input type="radio"/> Varies <input type="radio"/> Don't know		
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ● Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the overall undesirable effects of therapeutic footwear versus offloading devices as large as offloading devices are associated with increased healing of ulcers, large reduction in plantar pressure, may result in a large reduction in infections, may reduce amputations with little to no difference in quality of life (patient satisfaction with offloading intervention). Further, these desirable effects of offloading devices are augmented by desirable effects on cost-effectiveness.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <ul style="list-style-type: none"> ● Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	<p>We judged the overall certainty of evidence as low, as ulcer healing (primary outcome) had low certainty of evidence, whereas new lesions, amputations and quality of life had very low certainty of evidence, plantar pressures and infections had low certainty of evidence and costs had moderate certainty of evidence.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <ul style="list-style-type: none"> ● No important uncertainty or variability 	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ● Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ○ Don't know 	<p>We judged the balance of effects as favours offloading devices over therapeutic footwear, based on our above judgements that footwear has small desirable effects, which are outweighed by large undesirable effects.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ○ Negligible costs and savings ● Moderate savings ○ Large savings ○ Varies ○ Don't know 	<p>Based on 1 RCT reporting a moderate increase of the initial one-off material costs for offloading devices over the use of therapeutic footwear</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ● Very low ○ Low ○ Moderate ○ High ○ No included studies 	<p>Based on that one-off material costs were reported in only 1 RCT with high risk of bias and very serious imprecision, resulting in a very low certainty of evidence.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ● Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ○ No included studies 	<p>We judged cost-effectiveness favours offloading devices over therapeutic footwear, based on the one cost-effectiveness analysis rated at low risk of bias finding cost-effectiveness in favour of offloading devices.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input checked="" type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this intervention does appear to promote equity of healthcare as footwear, in general, are less costly to patients and health care providers than offloading devices.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on 1 RCT with high risk of bias and 2 non-controlled repeated measures studies of unknown bias. In summary, the studies found that offloading devices may result in little to no difference in patient satisfaction with therapeutic footwear, compared to offloading devices. There are no studies on acceptability of other key stakeholders, but, based on expert opinion, acceptability for clinicians may vary depending on the skills and resources available in the particular setting.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, this intervention is probably feasible to introduce into the healthcare system in most countries, as prefabricated footwear is less costly than offloading devices. However, fully custom-made footwear requires substantial economic resource and clinical expertise to produce, and may therefore not be feasible to introduce in all healthcare systems.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ●	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction of the recommendation. The decision for a strong recommendation was not unanimous, with the majority of members of the group voting for a strong recommendation and a minority of member(s) of the group voting for a conditional recommendation.

Justification

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 6

In a person with diabetes and a plantar forefoot or midfoot ulcer, should any other non-surgical offloading intervention be used over another non-surgical offloading intervention?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Any other non-surgical offloading intervention (other than an offloading device or footwear)
COMPARISON:	Another offloading intervention
MAIN OUTCOMES:	<p>Healed ulcer (critical), plantar pressure, weight-bearing activity, adherence, new lesions, falls, infections, amputations, quality of life, costs, cost-effectiveness or balance outcomes.</p> <p>Note: The below outcomes listed are only those critical or important outcomes our systematic review identified to have data reported for this comparison. There was no data reported for weight-bearing activity, falls, quality of life, costs of initial treatment, cost-effectiveness, or balance outcomes.</p> <p>Healed ulcer (for interventions of: Felted foam; and Wheelchairs); Plantar pressure (for interventions of: Felted foam; Gait retraining; Botulinum toxin injections; and Foam wound dressings); Adherence (for interventions of: Felted foam); New lesions (for intervention of: Felted foam); Infections (for interventions of: Felted foam; and Botulinum toxin injections); and Amputations (for interventions of: Wheelchairs).</p>
PERSPECTIVE:	Population
CONFLICT OF INTERESTS:	The group declare that they have no specific relevant competing interests for this question.

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged this as yes, as this was decided a priori for all clinical questions in the 2023 IWGDF guidelines given the considerable global burden of disease caused by diabetes-related foot ulcers.</p> <p>Note: We considered there was only enough research evidence to justify performing a Summary of Judgements evaluation and recommendation on the intervention of felted foam. Please see the accompanying additional considerations for further details on our group decision.</p>	<p>To address this question, the group considered there was only evidence to justify performing a Summary of Judgements evaluation and recommendation on the intervention of felted foam as it was the only applicable intervention addressing this question to have any data reported on the critical outcome of healing that potentially favoured the intervention. The other interventions with data either reported on critical outcomes that did not favour the intervention (i.e. wheelchairs) or did not report critical outcomes and the group felt did not have enough data that favoured the intervention for other important outcomes of the magnitude to develop summary of judgements or make a recommendation (i.e. gait retraining, Botulinum toxin injections, Foam wound dressings).</p>

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the overall desirable effects as small, based on the combined trivial-to-moderate desirable effects found in favour of felted foam applied to a removable ankle-high offloading device compared to a removable ankle-high offloading device alone on several outcomes of interest in our systematic review which aligned with our expert opinion, including the critical outcome of healed ulcers may result in little-to-no difference, but the important outcome of plantar pressure reduction may result in moderate desirable effects</p>	
<h3>Undesirable Effects</h3> <p>How substantial are the undesirable anticipated effects?</p>		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input checked="" type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the overall undesirable effects as trivial, based on the combined trivial undesirable effects (or little-to-no difference) found between felted foam applied to a removable ankle-high offloading device compared to a removable ankle-high offloading device alone on several outcomes of interest in our systematic review, including for the important outcome of adverse effects on new lesions and adverse events on infections.</p>	<p>We suggest however adding some additional implementation considerations with regard to the 'safe' application of felted foam (and particularly in low- and middle-income countries) to ensure minimal undesirable effects from new transfer lesions/skin tears or infections.</p>
<h3>Certainty of evidence</h3> <p>What is the overall certainty of the evidence of effects?</p>		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>We judged the overall certainty of evidence as very low, based on our assessments of very low certainty of evidence in our systematic review for the critical outcome of ulcers healed and for the other important outcomes of plantar pressure reduction, adverse effects and adverse events.</p>	
<h3>Values</h3> <p>Is there important uncertainty about or variability in how much people value the main outcomes?</p>		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	<p>We judged the values as having no important uncertainty or variability, based on our survey findings of all group members, 10 external clinical reviewers and 2 patient consumers with lived experience. Collectively these stakeholders rated the primary (critical) outcome of healed ulcers as the most critical outcome (median (IQR) 9 (8-9), on a scale of 1-9 (1 being least important and 9 being most critically important)). Furthermore, all additional important outcomes were selected by the same process with all having median scores of at least 6 (5-7) for balance to 8 (8-9) for adherence.</p>	
<h3>Balance of effects</h3> <p>Does the balance between desirable and undesirable effects favour the intervention or the comparison?</p>		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the balance of effects as probably favours the intervention, based on our above judgements of small desirable effects probably outweighing the trivial undesirable effects.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input checked="" type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the resources required as negligible costs and savings, based entirely on the group's expert opinion (see additional considerations) as there was no research evidence for initial costs or resources required identified in our systematic review.</p>	<p>We considered in our expert opinion, while felted foam is an additional cost on top of an offloading device and would require frequent replacement (at least weekly), from an offloading intervention perspective felted foam is inexpensive to purchase in low- and middle-income countries around the world and requires little additional skill to apply and as such requires negligible (and certainly not moderate) additional resources.</p>

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>We judged the certainty of evidence of resources required as very low, as it was based entirely on the group's expert opinion and knowledge of market prices for the felted foam as per the resources required section, as no research evidence for initial costs or resources required was identified in our systematic review.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> No included studies 	<p>We judged cost-effectiveness as no included studies, based on there being no included studies identified in our systematic review on cost-effectiveness , plus, we felt we did not have enough expert opinion to be able to make an informed judgement on cost-effectiveness for the felted foam intervention.</p>	
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Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input checked="" type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the impact on health equity as probably increased, based entirely on the group's expert opinion (see additional considerations) as there was no research evidence for equity identified in our systematic review.</p>	<p>We considered in our expert opinion, the impact on health equity is probably increased, due to felted foam being inexpensive, readily available around the world and requiring little skill to implement and use, thus felted foam should probably increase health equity in disadvantaged subgroups, and low- or middle- income countries.</p>

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged this intervention as probably yes for acceptability to key clinical and patient stakeholders, based on multiple published surveys of offloading practice around the world showing the use of felted foam is high in many countries, and our judgement that felted foam would probably increase health equity for disadvantaged groups, thus we considered felted foam should have a positive impact on acceptability.</p>	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged this intervention as probably feasible to implement, based on our above judgements and our expert opinion that this intervention requires negligible additional resources or skills to implement, probably improves health equity and is probably acceptable to most key stakeholders around the world, thus we considered felted foam to probably be feasible to implement.</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention <input type="radio"/>	Conditional recommendation against the intervention <input type="radio"/>	Conditional recommendation for either the intervention or the comparison <input type="radio"/>	Conditional recommendation for the intervention <input checked="" type="radio"/>	Strong recommendation for the intervention <input type="radio"/>
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Overall, after weighing up the Summary of Judgements table, we consider a conditional recommendation in favour of the intervention of felted foam in combination with a removable ankle-high device compared to a removable ankle-high device alone is justified, based on the group having judgements probably favouring or equivalent for the intervention for the majority of judgements, including importantly for the balance of effects, equity, acceptability and feasibility judgements in particular.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 7A

In a person with diabetes and a plantar forefoot or midfoot ulcer, should Achilles tendon lengthening be used over other (surgical or non-surgical) offloading interventions?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Achilles tendon lengthening surgical offloading intervention
COMPARISON:	Other offloading interventions
MAIN OUTCOMES:	Healed ulcer (at 7 months); Plantar pressure (forefoot after treatment); Plantar pressure (rearfoot after treatment); Weight-bearing activity (walking velocity after treatment); Sustained healing (reduced ulcer recurrence); Adverse effects (of new ulcers or lesions); Adverse effects (of new heel ulcers); Adverse effects (of falls); Adverse events (of infections); Adverse events (of amputations); Quality of life; Costs; Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate	We judged the overall desirable effect as moderate, based on our systematic review finding the intervention of Achilles tendon lengthening in combination with a TCC showing small increases in the proportion of ulcers healed compared to a TCC alone (RR 1.10, 0.96-1.27; p=0.18; Moderate CoE),	

<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>large increases in sustained healing once healed (RR 3.41, 1.42-8.18, p=0.006; Moderate CoE), large decreases in forefoot plantar pressure (MD 218 kPa lower, 410-26 lower; p=0.03; Low CoE), moderate decreases in new lesions (RR 0.71, 0.22-2.28; p=0.56; Very low CoE) and large decreases in amputations (RR 0.35, 0.01-8.38; p=0.52; Very low CoE). Thus, in combination we judge the overall desirable effects of these outcome to be moderate.</p>	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input checked="" type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the undesirable effects as moderate, based on our systematic review finding the intervention vs control had large increases in new rearfoot ulcers (RR 9.56, 0.54-170.46; p=0.12; Moderate CoE) and large increases in falls (RR 5.31, 0.27-106.46; p=0.27; Low CoE) and infections (RR 3.19, 0.13-75.43; p=0.47; Low CoE).</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input checked="" type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>We judged the overall certainty of evidence as moderate. This is based on the critical outcomes of ulcers healed and sustained healing having moderate certainty of evidence.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the balance of effects as probably favours the intervention, based on our above judgements that the moderate desirable effect probably outweighs the moderate risk of undesirable effects.</p>	<p>Note although the absolute number of heal ulcers for the control group is 0 (zero) and for the intervention group is 4, Revman is able to calculate an RR by automatically providing 0.5 events instead of the 0 events for the control group.</p>
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input checked="" type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the resources required as moderate based on the panel's expert opinion, as there was no evidence on cost identified in our Summary of Findings table. The intervention, Achilles tendon lengthening requires resources like OR, skilled surgeon, hardware, post-op care etc., that are not available in all settings.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>We judged the certainty of evidence as low, as it is entirely based on the panel's expert opinion and knowledge of the resources needed for surgical procedures, as no evidence for costs was identified in our Summary of Findings table.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	<p>We judged cost-effectiveness probably favours the intervention, based on our expert opinion, as no evidence for cost-effectiveness was identified in our Summary of Findings table. This is based on the moderate desirable effects, moderate additional cost and the moderate undesirable effects of the intervention.</p>	

Equity		
What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the impact of health equity as probably reduced as the intervention Achilles tendon lengthening is not available everywhere. This is based entirely of our expert opinion as there is no evidence on equity in our Judgement of Findings.</p>	
Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged this intervention as probably no for acceptability to key clinical and patient stakeholders based on our expert's opinion. There may be differences in the acceptability between different key stakeholders. This is based on the limited access to the intervention, the small effect of the intervention on healed ulcer and the positive effect on sustained healing, while the undesirably effect is moderate, yet the absolute number is low.</p>	<p>It is the opinion of the expert's panel that the effect on balance may contribute negatively to the acceptance of the intervention, yet there is no data to support this in the Summary of Findings</p>
Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the feasibility to implement this intervention as varies, based on our above judgements and our expert's opinion that it requires additional resources, equity is probably reduced, and as such may not be feasible to implement everywhere</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate Costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Surgical procedures to promote healing of diabetic foot ulcers or/and to sustain healing, are, per se, not first-line options in the treatment line. The only RCT (Mueller, 2003) included in this study, included recurrent forefoot ulcers, while the case series all were on recalcitrant ulcers except Meschkin, 2020, where there is no information. It is the opinion of the expert's group that Achilles tendon Lengthening should be considered after a reasonable time of conservative treatment without healing of the ulcer. ATL should also be considered in recurrent ulcers due to the effect of sustained healing of the ATL procedure.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 7B

n a person with diabetes and a plantar forefoot or midfoot ulcer, should metatarsal head resection be used over any other offloading interventions?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Metatarsal head resection surgical offloading interventions
COMPARISON:	Other offloading interventions
MAIN OUTCOMES:	Healed ulcer (at 4-17 months); Plantar pressure (at forefoot after treatment); Weight-bearing activity (self-reported limitations of activities (scale 1-4, 1 least satisfied - 4 most satisfied)); Sustained healing (at 6-17 months); Adverse effects (of new ulcers or lesions); Adverse effects (of falls); Adverse events (of infections); Adverse events (of amputations); Quality of life (satisfaction at conclusion of treatment (scale 1-10, 1 least satisfied -10 most satisfied); Quality of life (self-reported discomfort during healing time (scale 1-4, 1 least satisfied - 4 most satisfied); Costs (over the treatment period); Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the overall desirable effect as moderate, based on the Summary of Findings, with a RR of healing of the ulcer of 1.33 (1.12-1.58) and a RR 1.21, (1.09-1.35) on sustained healing, however, the certainty of evidence is low.</p>	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the undesirable effect as small, based on the Summary of Findings. Anecdotally, transfer lesions may occur.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	<p>We judged the overall certainty of evidence as low. This is based on Summary of Findings where the certainty of evidence is very low to low.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ● Probably favours the intervention ○ Favours the intervention ○ Varies ○ Don't know 	<p>We judged the balance of effects as probably favours the intervention, based on our above judgements of the moderate desirable effect on healed ulcers and sustained healing may outweigh the small undesirable effect.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ● Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know 	<p>We judged the resources required as moderate based on the panel's expert opinion, as there was no evidence on cost identified in our Summary of Findings table. The intervention, metatarsal head resection, requires resources like OR, skilled surgeon, hardware, post-op care etc., that are not available in all settings.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>We judged the certainty of evidence as low, as it is entirely based on the panel's expert opinion and knowledge of the resources needed for surgical procedures, as no evidence for costs was identified in our Summary of Findings table.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ● Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ○ No included studies 	<p>We judged cost-effectiveness probably does not favour either the intervention or the comparison. In Summary of Findings one observational study suggest a reduced cost over the treatment period, but the effect is not estimable, and the certainty of evidence is very low.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	We judged the impact of health equity as probably reduced as the intervention metatarsal head resection is not available everywhere and has moderate cost. This is based entirely of our expert opinion as there is no evidence on equity in our Judgement of Findings.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	We judged this intervention as probably yes for acceptability to key clinical and patient stakeholders based on our expert's opinion provided the patient has gone through a course of conservative therapy. There may be differences in the acceptability between different key stakeholders. This is based on the limited access to the intervention, the small effect of the intervention on healed ulcer and the positive effect on sustained healing. One RCT reported of a small reduction of QOL during treatment and an increase of QOL after treatment. The certainty of evidence is low.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	We judged the feasibility to implement this intervention as varies, based on our above judgements and our expert's opinion that it requires additional resources, equity is probably reduced, and as such may not be feasible to implement everywhere	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Surgical procedures to promote healing of diabetic foot ulcers or/and to sustain healing, are, per se, not first-line options in the treatment line. The expert's panel emphasize that the indication for metatarsal head resection may include management of infection, as osteomyelitis or joint infection, as well as surgical offloading of a prominent metatarsal head. This makes the comparison to conservative treatment difficult. The magnitude of the undesirable effect may also vary due to the joint in question. It is expected that there is a higher risk of undesirable effect in the first metatarsal phalangeal joint than in second to fifth ray.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 7C

In a person with diabetes and a plantar forefoot or midfoot ulcer, should joint arthroplasty be used over any other offloading interventions?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related foot ulcer
INTERVENTION:	Joint arthroplasty surgical offloading interventions
COMPARISON:	Other offloading interventions
MAIN OUTCOMES:	Healed ulcer (at 6 months); Plantar pressure; Weight-bearing activity; Sustained healing; Adverse effects (on new ulcers or lesions); Adverse effects (on falls); Adverse events (on infections); Adverse events (on amputations); Quality of life; Costs; Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large	We judged the overall desirable effect as moderate, based on the Summary of Findings, with a RR of healing of the ulcer of 1.07 (0.89-1.28). The effect is based on 29 participants in one RCT and the certainty of evidence is moderate. The positive effect on sustained healing, with a RR of 1.19, 0.67-2.12 contribute to the overall desirable effect, as the possible effect of reducing amputations (RR 0.48	

<input type="radio"/> Varies <input type="radio"/> Don't know	(0.05-4.85).	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged, based on Summary of Findings, that the undesirable effect is small. Only two RCTs reported on infections and joint arthroplasties may result in little to no difference in infections. There is a poverty of studies reporting on other undesirably effects.</p>	<p>It is the experts opinion that undesirably effects may be under reported but we have no data to support this.</p>

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	<p>We judged the overall certainty of evidence as low. This is based on Summary of Findings where the, judged by the expert's opinion, all important desirably effects and undesirably effects, have low certainty of evidence.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the balance of effects as probably favours the intervention, based on our above judgements of the small desirable effect on healed ulcers may outweigh the low risk of undesirable effect. Although the RR of undesirably effect is 0.95 (0.44-2.05), the absolute number of heal ulcers is moderate (229 per 1,000).</p>	<p>The potential under reporting of other undesirably effects increases the risk of bias.</p>
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input checked="" type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the resources required as moderate based on the panel's expert opinion, as there was no evidence on cost identified in our Summary of Findings table. The intervention, joint arthroplasty requires resources like OR, skilled surgeon, hardware, post-op care etc., that are not available in all settings.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>We judged the certainty of evidence as low, as it is entirely based on the panel's expert opinion and knowledge of the resources needed for surgical procedures, as no evidence for costs was identified in our Summary of Findings table.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input checked="" type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	<p>We judged cost-effectiveness probably not favour either the intervention or the comparison, based on our expert opinion, as no evidence for costs was identified in our Summary of Findings table. This is based on the small effect on the outcomes (healed ulcer and sustained healing), moderate cost and the small undesirably effect of the intervention.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	We judged the impact of health equity as probably reduced as the intervention joint arthroplasty is not available everywhere and have moderate cost. This is based entirely of our expert opinion as there is no evidence on equity in our Judgement of Findings.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	We judged this intervention as probably no for acceptability to key clinical and patient stakeholders based on our expert's opinion. There may be differences in the acceptability between different key stakeholders. This is based on the limited access to the intervention, the small effect of the intervention on healed ulcer and the positive effect on sustained healing, while the undesirably effect is low.	The poverty of data for potentially undesirably effect increase the risk of bias
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	We judged the feasibility to implement this intervention as varies, based on our above judgements and our expert's opinion that it requires additional resources, equity is probably reduced, and as such may not be feasible to implement everywhere	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Surgical procedures to promote healing of diabetic foot ulcers or/and to sustain healing, are, per se, not first-line options in the treatment line. The expert's panel emphasize that the indication for joint arthroplasty, for a neuropathic hallux ulcer include limited range of motion of the first metatarsal phalangeal joint. In case of other deformities with a hallux ulcer, joint arthroplasty may not be indicated.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 7D

In a person with diabetes and a plantar forefoot or midfoot ulcer, should joint arthrodesis be used over any other offloading intervention?	
POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer
INTERVENTION:	Joint arthrodesis surgical offloading interventions
COMPARISON:	Other offloading interventions
MAIN OUTCOMES:	Healed ulcer (time-to-healing); Plantar pressure; Weight-bearing activity; Sustained healing; Adverse effects (on new ulcers or lesions); Adverse effects (on falls); Adverse events (on infections); Adverse events (on amputations); Adverse events (acute ankle joint arthropathy); Quality of life; Costs; Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know		

Undesirable Effects

How substantial are the undesirable anticipated effects?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 		

Certainty of evidence

What is the overall certainty of the evidence of effects?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 		

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input type="radio"/> No important uncertainty or variability 		

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 		

Resources required

How large are the resource requirements (costs)?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> Large costs<input type="radio"/> Moderate costs<input type="radio"/> Negligible costs and savings<input type="radio"/> Moderate savings<input type="radio"/> Large savings<input type="radio"/> Varies<input type="radio"/> Don't know		

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> Very low<input type="radio"/> Low<input type="radio"/> Moderate<input type="radio"/> High<input type="radio"/> No included studies		

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> Favours the comparison<input type="radio"/> Probably favours the comparison<input type="radio"/> Does not favour either the intervention or the comparison<input type="radio"/> Probably favours the intervention<input type="radio"/> Favours the intervention<input type="radio"/> Varies<input type="radio"/> No included studies		

Equity

What would be the impact on health equity?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> Reduced<input type="radio"/> Probably reduced<input type="radio"/> Probably no impact<input type="radio"/> Probably increased		

<input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know		
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Acceptability
 Is the intervention acceptable to key stakeholders?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		

Feasibility
 Is the intervention feasible to implement?

Judgement	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

The experts panel decided not to put forward a recommendation for this question, in correspondence with our 2019 guideline

Voting: Unanimous for not making a recommendation.

Justification

The only paper regarding joint arthrodesis is based on the population of Charcot midfoot deformities and diabetic foot ulcers. This paper is included in the Charcot group of recommendations.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 7E

In a person with diabetes and a plantar forefoot or midfoot ulcer, should metatarsal osteotomy be used over any other offloading interventions?

POPULATION:	People with a plantar forefoot diabetes-related ulcer
INTERVENTION:	Metatarsal osteotomy surgical offloading interventions
COMPARISON:	Other offloading interventions
MAIN OUTCOMES:	Healed ulcer (time-to-healing); Plantar pressure; Weight-bearing activity; Sustained healing (reduced ulcer recurrence); Adverse effects (of new ulcers or lesions); Adverse events (of infections); Adverse events (of amputations); Adverse effects (of falls); Quality of life; Costs; Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large 	We judged the overall desirable effect as moderate, based on the moderate desirable effect found in favour of metatarsal osteotomy compared to other off-loading interventions on several outcomes of interest in the Summary of Findings like healed ulcer, plantar pressure, and sustained healing. The intervention may reduce amputations, but the evidence is very uncertain.	

<input type="radio"/> Varies <input type="radio"/> Don't know		
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the overall undesirable effect as small, based on our assessments in the Summary of Findings, including new transfer ulcers and infections.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	<p>We judged the overall certainty of evidence as low based on our findings in Summary of Findings, as the certainty of the desirable effects are low to very low and the certainty of the undesirably effects are very low.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the balance of effects as probably favours the intervention, based on our above judgements of the small desirable effect on healed ulcers may outweigh the low risk of undesirable effect.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input checked="" type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the resources required as moderate based on the panel's expert opinion, as there was no evidence on cost identified in our Summary of Findings table. The intervention, metatarsal osteotomy, requires resources like OR, skilled surgeon, post-op care etc., that are not available in all settings</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>We judged the certainty of evidence as low, as it is entirely based on the panel's expert opinion and knowledge of the resources needed for surgical procedures, as no evidence for costs was identified in our Summary of Findings table.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input checked="" type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	<p>We judged cost-effectiveness does not favour either the intervention or the comparison, based on our expert opinion, as no evidence for costs was identified in our Summary of Findings table.</p>	

Equity		
What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the impact of health equity as probably reduced as the intervention metatarsal osteotomy is not available everywhere and have moderate cost. This is based entirely of our expert opinion as there is no evidence on equity in our Judgement of Findings.</p>	
Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged this intervention as probably no for acceptability to key clinical and patient stakeholders based on our expert's opinion. There may be differences in the acceptability between different key stakeholders. This is based on the limited access to the intervention, the little-to no effect of the intervention on healed ulcer and the positive effect on sustained healing.</p>	
Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the feasibility to implement this intervention as varies, based on our above judgements and our expert's opinion that it requires additional resources, equity is probably reduced, and as such may not be feasible to implement everywhere</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either	Probably favours intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate Costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Surgical procedures to promote healing of diabetic foot ulcers or/and to sustain healing, are, per se, not first-line options in the treatment line. The conditional recommendation for metatarsal osteotomy is limited to metatarsal 2-5. This is due to the increased risk of undesirable effects when performing the osteotomy on the first ray, judged by the expert's opinion. Additional, in case of infection in the distal part of the metatarsals or in the metatarsal phalangeal joint, consider using a metatarsal head resection instead (reference to Q7B).

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 7F

In a person with diabetes and a plantar forefoot or midfoot ulcer, should digital flexor tenotomy be used over any other offloading interventions?

POPULATION:	People with a plantar forefoot diabetes-related ulcer
INTERVENTION:	Digital flexor tenotomy surgical offloading interventions
COMPARISON:	Other offloading interventions
MAIN OUTCOMES:	Healed ulcer (at 12 months); Plantar pressure (at the ulcer site); Weight-bearing activity; Sustained healing; Adverse effects (of new ulcers or lesions); Adverse effects (of falls); Adverse events (of infections); Adverse events (of amputations); Quality of life (self-reported satisfaction after treatment); Costs; Balance;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate	We judged the desirable effect as moderate as 1 RCT and several non-controlled studies show that digital flexor tenotomy likely increases healed ulcers, reduces plantar pressure at the ulcer site and sustains healing. Digital flexor tenotomy may increase quality of life, while there is little to no	

<input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	<p>difference in amputations.</p>	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged the undesirable effect as small as digital flexor tenotomy may increase transfer lesions. There is likely not an increase in infections and likely little to no difference in balance.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input type="radio"/> Low <input checked="" type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	<p>We judged the overall certainty of evidence as moderate, based on our Summary of Findings of moderate certainty of evidence for healed ulcer, sustained healing, infections, amputations, and balance, and low to very low certainty of evidence on plantar pressure, transfer ulcer and quality of life.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ● Favours the intervention ○ Varies ○ Don't know 	<p>We judged the balance of effects as favours the intervention, based on our above judgements of moderate desirable effects probably outweighing the undesirably effect of transfer ulcers.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ● Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know 	<p>We judged the resources required as negligible costs and savings, based on the panel's expert opinion, as there was no evidence on costs identified in our Summary of Findings table.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>We judged the certainty of evidence as low, as it is entirely based on the panel's expert opinion and knowledge of the resources needed for small surgical procedures, as no evidence for costs was identified in our Summary of Findings table.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ● Probably favours the intervention ○ Favours the intervention ○ Varies ○ No included studies 	<p>We judged cost-effectiveness probably favours digital flexor tenotomy, based on our expert opinion, as no evidence for costs was identified in our Summary of Findings table. This is based on the moderate effect on the outcomes (healed ulcer and sustained healing), small cost and the small undesirably effect of the intervention.</p>	

Equity		
What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input checked="" type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged the impact on health equity as probably increased with this intervention of digital flexor tenotomy, again based entirely on our expert opinion, due to digital flexor tenotomy being comparatively inexpensive, readily available around the world and requiring little skill to implement and use, thus digital flexor tenotomies could have a positive impact on offloading in low- or middle-income countries.</p>	
Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged this intervention as probably yes for acceptability to key clinical and patient stakeholders, based on the expert's opinion and experience. Digital flexor tenotomy can be performed after a short introduction and requires a clean but not sterile environment. The adverse events are preventable and treatable. The effect on balance is negligible, a concern many patients express prior to the procedure.</p>	
Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judged this intervention as feasible to implement, based on our above judgements and our expert opinion that this intervention requires small extra resources or skills to implement, probably improves health equity and is probably acceptable to most key stakeholders around the world, thus we judge digital flexor tenotomy to be feasible to implement.</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ●
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction of the recommendation. The decision for a strong recommendation was not unanimous, with the majority of members of the group voting for a strong recommendation and a minority of member(s) of the group voting for a conditional recommendation.

Justification

Surgical procedures to promote healing of diabetic foot ulcers or/and to sustain healing, are, per se, not first-line options in the treatment line. However, in a person with diabetes and a neuropathic ulcer of the plantar or apex of digits 2-5 secondary to a flexible deformity, based on a recent RCT, it is fair to consider flexor tenotomy as a first line of treatment. This is based on the low risk of undesirable effects and the moderate desirable effects. The recommendation is limited to digit 2-5. This is based on the expert's opinion as neuropathic ulcers on the first toe may be caused of other deformities or limited joint motion. The first digit has been excluded in the recommendation as other deformities and limitations may contribute to the non-healing of ulcers at the hallux.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 8A

In a person with diabetes and a plantar forefoot or midfoot ulcer complicated by either mild infection or mild ischemia, should a non-removable knee-high offloading device be used over a removable offloading device?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer complicated by either mild infection or mild ischemia
INTERVENTION:	Non-removable knee-high offloading device
COMPARISON:	Removable offloading device
MAIN OUTCOMES:	Healed ulcer (with Non-removable knee-high offloading devices); Healed ulcer (with Removable offloading devices); Healed ulcer (with Removable knee-high offloading device); Resolution of infection; Adverse events of amputation (with Removable offloading devices);
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small	We judge the overall desirable effects as moderate based on one other controlled trial reporting that non-removable knee-high offloading devices compared to removable offloading devices may heal	

<ul style="list-style-type: none"> ● Moderate ○ Large ○ Varies ○ Don't know 	<p>more mildly-to-moderately infected diabetes-related foot ulcers and reduce the number of amputations.</p>	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large ○ Moderate ● Small ○ Trivial ○ Varies ○ Don't know 	<p>We judge the overall undesirable effects as small based on one other controlled trial reporting that non-removable knee-high offloading devices compared to removable offloading devices may result in a minor increase of time to healing of the ulcer.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>We judge the certainty of evidence as low due to only one other controlled trial reporting ulcer healing and amputations, with low certainty of evidence (for ulcer healing and amputation).</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ● No important uncertainty or variability 	<p>Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ● Probably favours the intervention ○ Favours the intervention ○ Varies ○ Don't know 	<p>Based on our above assessments of moderate desirable effects outweighing the small undesirable effects.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ○ Negligible costs and savings ● Moderate savings ○ Large savings ○ Varies ○ Don't know 	<p>Based on 4 trials with all but one reporting a moderate saving for the initial one-off material costs in favour of non-removable knee-high offloading devices.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>Based on our systematic review assessment that there was a low certainty of evidence for the (one-off material) costs outcome.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● No included studies 	<p>Although one cost-effectiveness analysis found moderate cost-effectiveness in favour of non-removable knee-high offloading devices in people with ulcers not complicated by infection or ischemia, these results may not be generalizable to ulcers with mild infection or mild ischemia as these ulcer may require more frequent changes of devices.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this intervention does not appear to promote equity of healthcare. 1. Likely to only be available to those with the ability to pay for the non-removable knee-high offloading devices. 2. Likely to only be available to those who have access to clinicians with the skills and resources to provide non-removable knee-high offloading devices. 3. Likely to be unavailable to those living in geographically disadvantaged locations, e.g. developing countries.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on multiple published surveys of clinical practice, acceptability to using non-removable knee-high offloading devices is low.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	In most countries this intervention is probably not feasible to introduce into the healthcare system, due to the lack of availability of the equipment and skilled clinicians required to implement non-removable knee-high offloading devices, plus these devices have not been routinely implemented in high-income countries.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

In a person with diabetes and a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischemia, consider using a non-removable knee-high offloading device to promote healing of the ulcer (Conditional; Low).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Our systematic review has found some evidence that non-removable knee-high devices are superior to removable devices for healing a plantar forefoot or midfoot diabetes-related ulcer complicated by either mild infection or mild ischemia. The improved healing is likely to be associated with increased levels of adherence for non-removable versus removable devices. It is possible that if removable devices were worn more frequently then there would be similar levels of healing between the devices. Recourses required, equity, acceptability and feasibility considerations will likely be the same for non-removable versus removable off-loading devices regardless of the presence of mild infection or ischemia, so we have referred to the evidence from question 1 when rating these outcomes. However, acceptability may be lower though, as clinicians may worry of not being able to keep a close eye on the foot when in a non-removable device. There is no data on the cost-effectiveness of the different devices to heal plantar forefoot or midfoot diabetes-related ulcer complicated by either mild infection or mild ischemia.

There is only one other controlled trial which reported ulcer healing and amputations in people with mildly-to-moderately infected diabetes-related foot ulcer. Thus, further research is needed to investigate non-removable knee-high devices vs removable devices for healing a plantar forefoot or midfoot diabetes-related ulcer complicated by either mild infection or mild ischemia.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 8B

In a person with diabetes and a plantar forefoot or midfoot ulcer complicated by both mild infection and mild ischemia or with moderate infection or moderate ischemia, should a removable offloading device be used over any other offloading intervention?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer complicated by both mild infection and mild ischemia or with moderate infection or moderate ischemia
INTERVENTION:	Removable offloading device
COMPARISON:	Any other offloading intervention
MAIN OUTCOMES:	Healed ulcer (with Non-removable knee-high offloading devices); Healed ulcer (with Removable offloading devices); Healed ulcer (with Removable knee-high offloading device); Resolution of infection (with novel TCC); Adverse effects of new ulcers or lesions (with novel TCC); Adverse effects of falls (with novel TCC); Adverse events of amputation (with Removable offloading devices);
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	We judge the overall desirable effects as moderate based on 1 RCT and a few non-controlled studies showing a positive effect on healing and on reducing amputation.	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input checked="" type="radio"/> Don't know	We don't know what the undesirable effects are as they were not reported in any of the studies.	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	We judge the certainty of evidence as low due to only 1 RCT and a few non-controlled studies.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on our above assessments of moderate desirable effects outweighing unknown undesirable effects.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input checked="" type="radio"/> Varies <input type="radio"/> Don't know 	<p>Resources vary, dependent on which removable offloading device and offloading intervention for the comparator is used.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>Is low as there are no studies on resources used.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> No included studies 	<p>No included studies to base on.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this intervention does not appear to promote equity of healthcare. 1. Likely to only be available to those with the ability to pay for the removable offloading devices. 2. Likely to only be available to those who have access to clinicians with the skills and resources to provide removable offloading devices. 3. Likely to be unavailable to those living in geographically disadvantaged locations, e.g. developing countries.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on multiple published surveys of clinical practice, acceptability to using removable offloading devices is reasonable.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	In most countries this intervention is probably feasible to provide to patients and introduce into the healthcare system.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

The change compared to the 2019 recommendation is that we now recommend any removable offloading device, not just knee-high. This is based on the study that shows no significant difference in healing between knee-high and ankle-high removable offloading to complicated foot ulcers.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 8C

In a person with diabetes and a plantar forefoot or midfoot ulcer complicated by both moderate infection and moderate ischemia or with severe infection or severe ischemia, should offloading be used over no offloading?

POPULATION:	People with a plantar forefoot or midfoot diabetes-related ulcer complicated by both moderate infection and moderate ischemia or with severe infection or severe ischemia
INTERVENTION:	Offloading intervention
COMPARISON:	No offloading
MAIN OUTCOMES:	Healed ulcer (with Non-removable knee-high offloading devices); Healed ulcer (with Removable offloading devices); Healed ulcer (with Removable knee-high offloading device); Resolution of infection (with novel TCC); Adverse effects of new ulcers or lesions (with novel TCC); Adverse effects of falls (with novel TCC); Adverse events of amputation (with Removable offloading devices);
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	No data available.	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	No data available.	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	The certainty of evidence is by definition very low, as we do not have any studies on this population and expert opinion classifies as very low evidence.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	No data available.	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input checked="" type="radio"/> Varies <input type="radio"/> Don't know 	Dependent on which offloading intervention is applied.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	No studies available so per definition low.	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> No included studies 	No data available.	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this intervention does not appear to promote equity of healthcare. 1. Likely to only be available to those with the ability to pay for the offloading intervention. 2. Likely to only be available to those who have access to clinicians with the skills and resources to provide the offloading intervention. 3. Likely to be unavailable to those living in geographically disadvantaged locations, e.g. developing countries.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Because also ulcers with moderate to severe infection and/or ischemia require offloading, this will be acceptable for most to all stakeholders.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	In most countries some form of offloading is feasible to prescribe to patients and to introduce into the healthcare system.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ●
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

The choice of offloading intervention, in the presence of both moderate infection and moderate ischaemia or with either severe infection or severe ischaemia, needs to consider patient's individual status, such as, patient's function, ambulatory status, and activity level. When the infection and ischemia are improved, the recommendations for mild to moderate infection or ischemia apply, or, when the infection or ischemia are resolved, the recommendations for non-complicated foot ulcers apply.

The recommendation is based on expert opinion as no studies are available. Thus, further research is needed to investigate offloading devices for healing a plantar forefoot or midfoot diabetes-related ulcer complicated by both moderate infection and moderate ischemia or with severe infection or severe ischemia.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 10

In a person with diabetes and a plantar rearfoot ulcer, should any one offloading intervention be used over another offloading intervention?

POPULATION:	People with a plantar rearfoot diabetes-related ulcer
INTERVENTION:	Non removable offloading intervention
COMPARISON:	Any removable offloading intervention
MAIN OUTCOMES:	Healed ulcer (at Rearfoot for Non-removable v Removable knee-high offloading devices); Time-to-healing (at Rearfoot for Non-removable offloading device vs Therapeutic footwear); Healed ulcer (at Rearfoot for Removable knee-high vs Removable ankle-high offloading); Plantar pressure (at Rearfoot for Non-removable vs Removable knee-high offloading devices); Plantar pressure (at Rearfoot for Removable knee-high vs Removable ankle-high offloading devices); Plantar pressure (at Rearfoot for Removable ankle-high offloading device vs Therapeutic footwear); Plantar pressure (at Rearfoot for Gait retraining vs No gait retraining); Plantar pressure (at Rearfoot after Achilles tendon lengthening+TCC vs TCC); Adverse events (for amputations at Rearfoot for Removable knee-high vs Removable ankle-high offloading);
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	Clinical outcomes from two studies of very low certainty of evidence. Improvement in number of ulcers and time to ulcer healing using non-removable offloading versus removable offloading	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input checked="" type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	Results from three observational studies with very low certainty of evidence report higher peak plantar pressures for the non-removable offloading device thus favouring the control group (removable devices). There is no data available comparing adverse events between the intervention and control.	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	Studies at high risk of bias, with large confidence intervals. Inconsistency in the outcomes for healing and plantar pressures.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ● Probably favours the intervention ○ Favours the intervention ○ Varies ○ Don't know 	Based on two studies with number of ulcers healed and time to healing.	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ○ Negligible costs and savings ● Moderate savings ○ Large savings ○ Varies ○ Don't know 	Based on 4 trials with all but one reporting a moderate saving for the initial one-off material costs in favour of non-removable offloading devices.	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	Based on our systematic review assessment that there was a low certainty of evidence for the (one-off material) costs outcome	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● No included studies 	There is one cost effectiveness analysis on these types of devices. This study utilised 13 trials however it only included four rearfoot ulcers, and the randomisation arm was not reported for three of these ulcers.	

Equity		
What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input checked="" type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Based on our expert opinion, as to our knowledge no evidence exists on equity for this comparison, this intervention does not appear to promote equity of healthcare. 1. Likely to only be available to those with the ability to pay for the non-removable offloading devices. 2. Likely to only be available to those who have access to clinicians with the skills and resources to provide non-removable offloading devices. 3. Likely to be unavailable to those living in geographically disadvantaged locations, e.g. developing countries</p>	
Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input checked="" type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>Based on multiple published surveys of clinical practice, acceptability to using non-removable offloading devices is low.</p>	
Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>In some countries the traditional TCC is probably not feasible to introduce into the healthcare system, due to the lack of availability of the equipment and skilled clinicians required to implement its use. However, in the context of this question that is comparing non-removable devices to other removable devices, some removable devices could readily be converted to a non-removable format using cast tape, straps or other methods.</p>	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

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).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Our systematic review has found some evidence that non-removable devices are superior to removable devices for healing neuropathic plantar rearfoot diabetes-related ulcers. The improved healing is likely to be associated with increased levels of adherence for non-removable versus removable devices. It is possible that if removable devices were worn more frequently then there would be similar levels of healing between the devices. Resources required, acceptability and feasibility considerations will be the same for non-removable versus removable offloading devices regardless of the site of ulceration, so we have referred to the evidence from question 1 when rating these outcomes. There is no data on the cost effectiveness of the different devices to heal plantar rearfoot diabetes-related ulcers.

We have decided not to make a recommendation around the use of different types of removable devices to offloading plantar rearfoot diabetes-related ulcer as there is insufficient high-quality evidence on the clinical outcomes. There is only one cohort study which reported ulcer healing, and time to healing in a subgroup of participants with rear foot ulcers. Participant numbers were small and unbalanced between the study arms; the groups were not well matched and the results for the control arm were combined for wheelchair and wheelchair plus offloading device. There have been four repeat measures studies which have shown that removable knee-high devices are superior to removable ankle-high devices, and ankle-high devices are superior to therapeutic footwear in reduction of plantar pressure. Further research is needed to assess whether this reduction in plantar pressure translates into improved clinical outcomes.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 11

In a person with diabetes and a non-plantar foot ulcer, should any one offloading intervention be used over another offloading intervention?	
POPULATION:	People with a non-plantar diabetes-related foot ulcer
INTERVENTION:	Any one offloading intervention
COMPARISON:	Another offloading intervention
MAIN OUTCOMES:	Healed ulcer (critical), plantar pressure, weight-bearing activity, adherence, new lesions, falls, infections, amputations, quality of life, costs, cost-effectiveness or balance outcomes.
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate	No studies were identified that specifically reported desirable outcomes for this question.	

<input type="radio"/> Large <input type="radio"/> Varies <input checked="" type="radio"/> Don't know		
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input checked="" type="radio"/> Don't know	No studies were identified that specifically reported undesirable outcomes for this question.	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input checked="" type="radio"/> No included studies	There is no research reporting the clinical outcomes for this question.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● Don't know 	<p>We judged the balance of effects as also being don't know, based on our above judgements of don't know for both the desirable and undesirable effects.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ● Varies ○ Don't know 	<p>Based on expert opinion, we judge the resources required vary depending on the choice of intervention.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ○ Low ○ Moderate ○ High ● No included studies 	<p>No studies.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● No included studies 	<p>No studies.</p>	

Equity What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, we judge the impact of the offloading intervention on equity to vary depending on the choice of intervention.	
Acceptability Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, we judge the acceptability of the offloading intervention to vary depending on the choice of intervention.	
Feasibility Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input checked="" type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, we judge the feasibility to implement the offloading intervention to vary depending on the choice of intervention as the costs, clinical training required and patient acceptability may vary between interventions.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ●
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CONCLUSIONS

Recommendation

In a person with diabetes and a non-plantar foot ulcer, use a removable offloading device, footwear modifications, toe spacers, orthoses, or flexor tendon tenotomy, depending on the type and location of the foot ulcer, to promote healing of the ulcer (Strong; Very low).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

A number of different interventions can be used to reduce pressures on the ulcer, depending on the type and location of the ulcer. For example, spacious footwear or footwear modifications can reduce pressure on ulcers on the foot margins and dorsal foot, toe spacers can reduce pressure on interdigital ulcers and orthoses can reduce pressure on ulcers on the back of the heel or medial/lateral foot when lying in bed. Furthermore, flexor tendon tenotomy can be used to reduce pressures on and promote healing of dorsal ulcers on deformed toes.

The recommendation is based on expert opinion as no studies are available. Thus, further research is needed to investigate offloading interventions for healing a non-plantar foot ulcer.

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 12

In a person with diabetes and a foot ulcer, should a combination of offloading interventions be used over a single offloading intervention?

POPULATION:	People with a diabetes-related foot ulcer
INTERVENTION:	Combination of offloading interventions
COMPARISON:	Single offloading intervention
MAIN OUTCOMES:	Healed ulcer (critical), plantar pressure, weight-bearing activity, adherence, new lesions, falls, infections, amputations, quality of life, costs, cost-effectiveness or balance outcomes.
PERSPECTIVE:	Population
CONFLICT OF INTERESTS:	The group declare that they have no specific relevant competing interests for this Question.

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p>We judged this as yes, as this was decided a priori for all clinical questions in the 2023 IWGDF guidelines given the considerable global burden of disease caused by diabetes-related foot ulcers.</p> <p>Note: Based on our systematic review, we considered that there was only evidence to justify performing a Summary of Judgements evaluation and recommendation on studies that primarily investigated surgical or other non-surgical offloading interventions in combination with another offloading intervention in comparison to a control that was a single offloading intervention from the combination. However, as all of these combined interventions have already been considered in other Summary of Judgements for other questions, the group considered that this question had already been addressed in recommendations made in those other questions and as such we decided not to perform Summary of Judgements for this question. Please see the accompanying additional considerations for further details on our group decision not to perform Summary of Judgements for this question and thus the rest of this Summary of Judgements form is not required or not applicable</p>	<p>We considered that this question has already been addressed, as all of these combined interventions have already been considered and recommendations made in other Summary of Judgements for other questions that address this question. Thus, we refer the reader to the earlier Summary of Judgements and recommendations for combined interventions, including: felted foam + removable device (Question 6); wheelchair + removable device (Question 6); heel cast + removable device (Question 11); Achilles tendon lengthening + TCC (Question 7A); metatarsal head resection + therapeutic footwear (Question 7B); joint arthroplasty + (non-)removable device (Question 7C); joint arthrodesis + TCC (Question 7D); digital flexor tenotomy + removable device (Question 7F).</p>

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know	As per our explanation in the problem section, this is now not applicable.	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know	Not applicable.	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies	Not applicable.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input type="radio"/> No important uncertainty or variability	Not applicable.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	Not applicable.	
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Resources required
How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	Not applicable.	

Certainty of evidence of required resources
What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	Not applicable.	

Cost effectiveness
Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> No included studies 	Not applicable.	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> Reduced<input type="radio"/> Probably reduced<input type="radio"/> Probably no impact<input type="radio"/> Probably increased<input type="radio"/> Increased<input type="radio"/> Varies<input type="radio"/> Don't know	Not applicable.	

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> No<input type="radio"/> Probably no<input type="radio"/> Probably yes<input type="radio"/> Yes<input type="radio"/> Varies<input type="radio"/> Don't know	Not applicable.	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"><input type="radio"/> No<input type="radio"/> Probably no<input type="radio"/> Probably yes<input type="radio"/> Yes<input type="radio"/> Varies<input type="radio"/> Don't know	Not applicable.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

No recommendation made.

Voting: Unanimous for not making a recommendation.

Justification

We considered that this question has already been addressed in earlier questions, as all of these combined interventions have already been considered and recommendations made in other Summary of Judgements for other questions that address this question. Thus, we refer the reader to the earlier Summary of Judgements and recommendations for combined interventions, including: felted foam + removable device (Question 6); wheelchair + removable device (Question 6); heel cast + removable device (Question 11); Achilles tendon lengthening + TCC (Question 7A); metatarsal head resection + therapeutic footwear (Question 7B); joint arthroplasty + (non-)removable device (Question 7C); joint arthrodesis + TCC (Question 7D); digital flexor tenotomy + removable device (Question 7F).

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 13

In a person with diabetes and a foot ulcer, should educational or psychological interventions along with an offloading intervention be used over an offloading intervention alone?

POPULATION:	People with a diabetes-related foot ulcer
INTERVENTION:	Educational or psychological interventions along with an offloading intervention
COMPARISON:	An offloading intervention alone
MAIN OUTCOMES:	Healed ulcer (critical), plantar pressure, weight-bearing activity, adherence, new lesions, falls, infections, amputations, quality of life, costs, cost-effectiveness or balance outcomes. Note: There was no evidence identified in our systematic review data for any outcome addressing the comparisons in this question.
PERSPECTIVE:	Population
CONFLICT OF INTERESTS:	The group declare that they have no specific relevant competing interests for this Question.

ASSESSMENT

Problem		
Is the problem a priority?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	We judged this as yes, as this was decided a priori for all clinical questions in the 2023 IWGDF guidelines given the considerable global burden of disease caused by diabetes-related foot ulcers.	
Desirable Effects		
How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input checked="" type="radio"/> Don't know	We judged the overall desirable effects as don't know, based on there being no included studies identified in our systematic review on any outcomes, plus, although we felt that education or psychological interventions are potentially important, we felt we did not have enough expert opinion to be able to make an informed judgement on the desirable effects for educational or psychological interventions along with an offloading intervention.	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	<p>We judged the overall undesirable effects also as don't know, based on there being no included studies identified in our systematic review on any outcomes, plus, again we felt we did not have enough expert opinion to be able to make an informed judgement on the undesirable effects for educational or psychological interventions along with an offloading intervention.</p>	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input checked="" type="radio"/> No included studies 	<p>We judged the certainty of evidence as no included studies, based on there being no included studies on educational or psychological interventions along with an offloading intervention.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	<p>We judged the values as having no important uncertainty or variability, based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.</p>	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	<p>We judged the balance of effects as also being don't know, based on our above judgements of don't know for both the desirable and undesirable effects.</p>	

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	<p>We judged the resources required also as don't know, based on there being no included studies identified in our systematic review on initial costs or resources required outcomes, plus, again we felt we did not have enough expert opinion to be able to make an informed judgement on the resources required for educational or psychological interventions along with an offloading intervention.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input checked="" type="radio"/> No included studies 	<p>We judged the certainty of evidence as no included studies, based on there being no included studies on resources required outcomes for educational or psychological interventions along with an offloading intervention.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> No included studies 	<p>We judged the cost-effectiveness also as no included studies, based on there being no included studies identified in our systematic review on cost-effectiveness outcomes, plus, again we felt we did not have enough expert opinion to be able to make an informed judgement on the cost-effectiveness of educational or psychological interventions along with an offloading intervention.</p>	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased 	<p>We judged the impact on health equity also as don't know, based on there being no included studies identified in our systematic review on initial costs or resources required outcomes, plus, again we felt we did not have enough expert opinion to be able to make an informed judgement on the impact on equity for educational or psychological interventions along with an offloading intervention.</p>	

<input type="radio"/> Varies <input checked="" type="radio"/> Don't know		
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Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input checked="" type="radio"/> Don't know	We judged the impact on acceptability also as don't know, based on there being no included studies identified in our systematic review on initial costs or resources required outcomes, plus, again we felt we did not have enough expert opinion to be able to make an informed judgement on the impact on acceptability for educational or psychological interventions along with an offloading intervention.	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input checked="" type="radio"/> Don't know	We judged the impact on feasibility also as don't know, based on there being no included studies identified in our systematic review on initial costs or resources required outcomes, plus, again we felt we did not have enough expert opinion to be able to make an informed judgement on the impact on feasibility for educational or psychological interventions along with an offloading intervention.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

No recommendation made.

Voting: Unanimous for not making a recommendation.

Justification

We were unable to make a recommendation to address this question as there were no included studies on this comparison identified in the systematic review and very limited expert experience/opinion to the group's knowledge. Thus, we simply don't know the desirable effects, undesirable effects, balance of effects, resources required, cost-effectiveness, equity, acceptability and feasibility judgments, and in turn have no judgements in which to make a recommendation. However, we strongly recommend research is needed on educational or psychological interventions along with an offloading intervention to provide data to address this important question in future as these interventions have shown promise in other areas of diabetes and diabetes-related foot disease care

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

CLINICAL QUESTION 14

In a person with diabetes and a foot ulcer, should an offloading intervention for the contralateral limb along with an offloading intervention for the ipsilateral limb be used over only an offloading intervention for the ipsilateral limb?

POPULATION:	People with a diabetes-related foot ulcer
INTERVENTION:	An offloading intervention for the contralateral limb along with an offloading intervention for the ipsilateral limb
COMPARISON:	Only an offloading intervention for the ipsilateral limb
MAIN OUTCOMES:	Plantar pressure (at forefoot with removable knee-high devices); Plantar pressure (at forefoot with removable ankle-high devices); Quality of life (perceived comfort with removable knee-high devices); Quality of life (perceived comfort with removable ankle-high devices); Balance ;
SETTING:	
PERSPECTIVE:	Population
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	A priori decided for all clinical questions given the burden of diabetes-related foot ulcers.	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Trivial <input checked="" type="radio"/> Small	We judge the desirable effects to be small based on one observational study finding that use of contralateral shoe lift in combination with a removable knee-high or ankle-high offloading device on	

<ul style="list-style-type: none"> <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	the ipsilateral leg, compared to no shoe lift, resulted in little-to-no differences in plantar forefoot pressure, small improvements of perceived comfort, and improvement of balance	
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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input checked="" type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know 	The only study comparing contralateral shoe lift in combination with a removable offloading device compared to a removable offloading device alone found no undesirable effects of the intervention. We do note very small increases in peak pressure possible in the ipsilateral foot when using a contralateral shoe lift, based on data from one study	

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	We judge the certainty of evidence as very low as there is no data on ulcer healing and the other outcomes had evidence of very low certainty.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Important uncertainty or variability <input type="radio"/> Possibly important uncertainty or variability <input type="radio"/> Probably no important uncertainty or variability <input checked="" type="radio"/> No important uncertainty or variability 	Based on the primary (critical) outcome of healed ulcers being rated as the most important outcome by our surveys of the panel, ~10 external clinical reviewers and 2 patient consumers with lived experience.	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input checked="" type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>We judge the balance of effects to probably favouring the intervention based on several, mostly small, desirable effects and no reported undesirable effects.</p>	
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Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large costs <input type="radio"/> Moderate costs <input checked="" type="radio"/> Negligible costs and savings <input type="radio"/> Moderate savings <input type="radio"/> Large savings <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Based on expert opinion, we judge the additional cost of providing an offloading intervention to the contralateral limb as negligible, as compared to only providing an offloading intervention to the ipsilateral limb.</p>	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input checked="" type="radio"/> Very low <input type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies 	<p>Based on expert opinion and no experimental studies on costs for contralateral offloading</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Favours the comparison <input type="radio"/> Probably favours the comparison <input type="radio"/> Does not favour either the intervention or the comparison <input type="radio"/> Probably favours the intervention <input type="radio"/> Favours the intervention <input type="radio"/> Varies <input checked="" type="radio"/> No included studies 		

Equity		
What would be the impact on health equity?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Reduced <input type="radio"/> Probably reduced <input checked="" type="radio"/> Probably no impact <input type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, we judge the intervention to probably have no impact on equity as the cost of providing an offloading intervention to the contralateral limb is negligible and availability is high.	
Acceptability		
Is the intervention acceptable to key stakeholders?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, we judge the intervention to probably be acceptable to key stakeholders as, for example, shoe lifts can be provided without much clinical training and seems to have no substantial undesirable effects on patients.	
Feasibility		
Is the intervention feasible to implement?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	Based on expert opinion, we judge the intervention to probably be feasible to implement due to low costs, high availability, high acceptance and mostly positive effects.	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

In a person with diabetes and a foot ulcer for which a knee-high or ankle-high offloading device is used, consider also using a shoe lift on the contralateral limb to improve the person's comfort and balance with walking in the device (Conditional; Very low).

Voting: Unanimous for the direction and the strength of the recommendation.

Justification

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

Definitions for the items (criteria) used in these Summary of Judgement tables (obtained from:

<https://gdt.gradepro.org/app/handbook/handbook.html#h.xr5ac2p2khuq>)

Criteria	Questions	Explanations
How substantial are the desirable anticipated effects?	How substantial (large) are the desirable anticipated effects (including health and other benefits) of the option (taking into account the severity or importance of the desirable consequences and the number of people affected)?	The larger the benefit, the more likely it is that an option should be recommended.
How substantial are the undesirable anticipated effects?	How substantial (large) are the undesirable anticipated effects (including harms to health and other harms) of the option (taking into account the severity or importance of the adverse effects and the number of people affected)?	The greater the harm, the less likely it is that an option should be recommended.
Do the desirable effects outweigh the undesirable effects?	Are the desirable effects large relative to the undesirable effects?	The larger the desirable effects in relation to the undesirable effects, taking into account the values of those affected (i.e. the relative value they attach to the desirable and undesirable outcomes) the more likely it is that an option should be recommended.
How large are the resource requirements?	How large an investment of resources would the option require or save?	The greater the cost, the less likely it is that an option should be a priority. Conversely, the greater the savings, the more likely it is that an option should be a priority.
How large is the incremental cost relative to the net benefit?	Is the cost small relative to the net benefits (benefits minus harms)?	The greater the cost per unit of benefit, the less likely it is that an option should be a priority.
What would be the impact on health inequities?	Would the option reduce or increase health inequities?	Policies or programmes that reduce inequities are more likely to be a priority than ones that do not (or ones that increase inequities).
Is the option acceptable to key stakeholders?	Are key stakeholders likely to find the option acceptable (given the relative importance they attach to the desirable and undesirable consequences of the option; the timing of the benefits, harms and costs; and their moral values)?	<p>The less acceptable an option is to key stakeholders, the less likely it is that it should be recommended, or if it is recommended, the more likely it is that the recommendation should include an implementation strategy to address concerns about acceptability. Acceptability might reflect who benefits (or is harmed) and who pays (or saves); and when the benefits, adverse effects, and costs occur (and the discount rates of key stakeholders; e.g. politicians may have a high discount rate for anything that occurs beyond the next election). Unacceptability may be due to some stakeholders:</p> <ul style="list-style-type: none"> • Not accepting the distribution of the benefits, harms and costs • Not accepting costs or undesirable effects in the short term for desirable effects (benefits) in the future • Attaching more value (relative importance) to the undesirable consequences than to the desirable consequences or costs of an option (because of how they might be affected personally or because of their perceptions of the relative importance of consequences for others) • Morally disapproving (i.e. in relationship to ethical principles such as autonomy, nonmaleficence, beneficence or justice)
Is the option feasible to implement?	Can the option be accomplished or brought about?	The less feasible (capable of being accomplished or brought about) an option is, the less likely it is that it should be recommended (i.e. the more barriers there are that would be difficult to overcome).

