Author’s response to reviews

Title: Diabetic Foot Australia guideline on footwear for people with diabetes

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Version: 1 Date: 20 Oct 2017

Author’s response to reviews:

Dear editor,

We would like to thank you and the reviewers for assessing our paper. Please find our point-by-point response below (answers in red). Lines indicated refer to the lines in the manuscript with track changes.

We are delighted to resubmit our revised manuscript for your consideration and we very much look forward to your response.
With kind regards, on behalf of all co-authors,

Jaap van Netten

Reviewer reports:

Reviewer #1: Firstly, I would like to take this opportunity to congratulate you on undertaking an important piece of work in this area. Consequently, I would very much like to see this article/guideline published but would respectfully request the following items to be addressed:

Response: We thank the reviewer for their lovely compliments.

1. Pp3 line 77 change "stress" to "stresses", given the multifactorial nature of this action which can include friction, pressure over area (force) as you so correctly indicated within the piece.

Response: We thank the reviewer for picking this up and have changed this accordingly throughout the manuscript

2. Consider a finesse relating to the statement made in line 80/1, re. barefoot walking as this does not automatically precipitate ulceration and I feel that a little more detail here would assist your argument.

Response: We appreciated this comment from the reviewer and have finessed this statement on barefoot walking to link it more directly and accurately with increased magnitudes of repetitive stresses that then may lead onto development of DFU (Lines 84-86):

“Use of inappropriate footwear or walking barefoot typically increases the magnitude of the local mechanical repetitive stresses on the foot that are leading causes of the development of diabetic foot ulceration”

3. A little more detail on appropriate socks may be beneficial re thickness, double skinned/lined and activity levels etc.

Response: We appreciate this suggestion from the review and have added some detail on appropriate socks as suggested (Lines 210-212):

“Further, advise people with diabetes to wear socks made of mostly natural materials (to prevent undue moisture accumulation), that are seamless (to prevent undue repetitive stresses) and do not have elasticated cuffs (to prevent undue oedema).”
4. In places there appears to be a paucity of references i.e. pp7 low risk ulceration

Response: We thank the reviewer for raising this point. We agree and have added references to overcome this shortcoming. However, this unfortunately is a field where there is a paucity of literature. As identified in the systematic review by Van Netten and colleagues on interventions to prevent foot ulceration, the vast majority of literature focuses on people at high-risk, not at those at low-risk. The statements in this paragraph are more based on expert opinion. In an official guideline following the GRADE guideline methodology, these would be named “Good practice recommendations”. For such recommendations evidence is limited, because it’s standard practice. We have added this as a limitation to the discussion (Lines 524-528):

“A third is the limited evidence base with regard to the recommendations for people at low-risk of ulceration [17, 41]. These recommendations might be seen as “good practice statements”, a terminology used in official guideline development for recommendations that are predominantly based on expert opinion and standard of practice, when limited evidence is available [51].”

5. I would value expert patient input on the term "diabetic foot remission", as whilst I totally agree with the concept the terminology seems slightly at odds with the current public health stance for motivating individuals living with diabetes.

Response: We agree that patient input would be valuable. If provided, probably not just on the term “diabetic foot remission”, but on the entire guideline. That is, however, outside the scope of the current paper. We have added this to the limitations and recommended in future guidelines patient advocates are included in the development (Lines 522-524):

“A second is that no patient advocates were involved in its creation. This is a consequence of not following a specific guideline methodology, and we hope that this will be done in the next update of the NHMRC guideline [31].”

With regard to the public stance on motivating individuals living with diabetes: the term “remission” comes from both the cancer and the rheumatoid arthritis field amongst others. In both fields, this term is well accepted by patients and the general public, as it refers (especially in rheumatoid arthritis) to an absence of a disease’s exacerbation and not to the disease itself. In our opinion, this is similar to a foot being in remission; it does not refer to diabetes or living with diabetes, but to the complication. We also point out the cited high quality papers that have introduced this concept in the diabetic foot field to highlight this is a concept gaining traction and not our original concept.

We thank the reviewer for this great point. We will take the patient involvement aboard when any new Australian guideline on diabetic foot disease will be created.

6. Can you confirm that in line 266 the paper is not stating that a pressure below 200 kPa does not induce ulceration
Response: We confirm. To make this clear, we have added the following sentence (Lines 320-321):

“When such footwear is being worn by patients, the risk of re-ulceration is smaller.”

7. Given the guidelines recommendations and the general awareness of the podiatry educational standards, is it likely that this guideline can be delivered and if not what training may have to be undertaken. It is noted, that you have stated that this maybe beyond the scope of this piece but without some insight into this area it weakens the remit and translation of this work.

Response: Again a well-raised and important point. In our opinion, this can all be delivered. The exception is probably the recommendation with regard to “demonstrated plantar pressure”, as measuring the demonstrated reduction of plantar pressure with offloading is currently not standard practice in Australia. We discussed this in the paper.

However, for the interest of the reviewer, in addition we are now seeing early changes taking place, with both podiatry students and podiatrists starting to get familiar with plantar pressure measurements. From the workshops on this topic given by various authors of this paper, we think we can state that even this recommendation can be delivered with minimal training.

8. Table 4 was a little confusing, namely points 1-3 i.e. "replacement of top cover" - with what?

Response: Thanks for asking us to clarify this. It is meant “with a new top cover of the same material”, we have added this now in the Legend of this Table.

9. Given the opening comments regarding the percentage of individuals who develop ulceration, is there a rough estimation of the cost and economic impact of prescription footwear for those with a history of ulceration and or high risk? This may have an important impact upon the feasibility of implementing this guideline from a fiscal stance.

Response: We very much thank the reviewer for this valuable point, as it was not something we had originally considered. We have added to the limitations section that there is no cost-effectiveness analysis data on specific foot interventions to our knowledge. However, we have also taken the opportunity to add detail on a recent Australian cost-effectiveness analysis that did included appropriate footwear as one aspect of a suite of evidence-based optimal diabetic foot care that showed significant reductions in patient costs compared with standard Australian care (Lines 530-536):

“Finally, we are unaware of cost-effectiveness information for any of the proposed footwear interventions [17], and thus no such specific information can be added to this guideline. However, a recent Australian cost-effectiveness analysis reported appropriately prescribed footwear as part of a suite of optimal diabetic foot care practice was always cheaper than
standard care, and with the high costs associated with foot ulceration [1, 52, 53], it is likely that preventative footwear efforts in this regard will be cost-saving [41].”

10. Given the importance stressed upon appropriate footwear fit there does not appear to be an educational tool which can be imparted to the patient when purchasing footwear, particularly for depth. Therefore, can at least the advice given to the patient be standardised in some manner. Response: We thank the reviewer for highlighting this point and reiterate that as stated in the methods, this guideline is targeted at a health professional audience and not a patient audience, so we will not be presenting advice to patients in this guideline. To somewhat standardize the advice health professionals may give to individual patients, taking into account that each foot is unique and needs to be assessed as such, we have provided the description of “Depth should accommodate the toes to move freely without causing pressure at either the medial, lateral or dorsal side” in Table 1. We have also added a little more detail on the Brannock device and new emerging foot scanning devices, but in our opinion a clinical assessment of depth is still required until emerging devices are validated (Lines 388-391):

“Although new scanning devices are becoming available to measure foot shape, we still suggest depth requires clinical assessment until accuracy of these devices can be independently quantified, taking into account that people with peripheral neuropathy cannot feel whether depth is accurate.”

11. Can a specific review be given for prescription footwear at a minimum of 12/18 months given the wound healing/remodelling phase post ulceration.

Response: We thank the reviewer for the really interesting concept of taking the skin remodeling phase into account in the provision of footwear. We believe it is a novel concept that is worth investigating moving forward. However, with the evidence we have available at present, we would prefer to remain with the recommendation based on the strongest evidence which is to review footwear every three months as per the pivotal trials performed by Sicco Bus et al, rather than adding a 12/18 months review in as well.

When footwear is reviewed every three months this should also automatically include an assessment of the foot after 12/18 months. However, if we specifically state another specific review period at 12/18 months, this might confuse readers, and might give insurance companies or similar bodies a reason to state that it is sufficient to review every 12/18 months. We really want everyone to read that review is needed every 3 months to ensure footwear is adequate.

12. Finally, I would like to say how pleased I was to see you inclusion of the individual's motivation/compliance factors and how sensibly this was discussed.

Response: Thank you, that’s great to hear.
Reviewer #2: I respect the tremendous depth of knowledge held by the authors in this field. Bus
in particular, has published important original research in this field as well as being the main
author on the IWGDF guidance. The IWGDF guidance documents provide very clear and freely
accessible information on this topic.

Response: We thank the reviewer for the compliment. The IWGDF guidelines are indeed freely
available, but the recommendations and considerations on footwear in our submitted manuscript
we believe are more extensive and provide additional detail compared to the IWGDF guideline.

2. However, for this current article to be a useful Australian guideline and meet its "...hope to
ensure that all Australians with diabetes are provided with appropriate footwear" and "reduce the
national burden of diabetic foot disease" I believe the authors need to;

1) Identify and summarise any new information which we need to translate into practice
from research conducted since the time of last publication (2013, they refer to) and

2) Contextualise the content from International guidelines and research for the Australian
audience

Response: We thank the reviewer for these very good points and we have taken the opportunity
kindly presented by the reviewer to further highlighted the new pivotal literature (studies,
systematic reviews and guidelines) that have been published in this area since the last Australian
footwear guideline in 2013, plus specific important new recommendations emanating from the
new literature in a number of sections in this guideline that were not in the 2013 guideline due to
lack of evidence at the time.

Please see the Background (Lines 91-96): “Since this publication, pivotal new studies [9, 17-30]
and international guidelines [10, 14, 15] have been published on footwear for people with
diabetes. This new literature provides a stronger evidence-base for the effectiveness of footwear
in ulcer prevention for people with diabetes, new data-driven directions for the prescription of
footwear, and new evidence on the importance of adherence to wearing footwear [9, 17-30].”

Methods (Line 106-114): “Information from the 2013 footwear guideline was updated first by
the primary author after reviewing and incorporating any new footwear-related recommendations
from the most recent Australian National Health and Medical Research Council (NHMRC)
diabetic foot guideline [31] and the International Working Group on the Diabetic Foot (IWGDF)
guidance documents [10, 14, 15]. The primary author then reviewed and incorporated common
findings from all recent systematic reviews on footwear interventions for people with diabetes
[17-22], recent randomized controlled trials included in these reviews [23, 24], and finally any
further studies obtained from hand searching reference lists of these articles and an additional
non-systematic search of the literature [9, 25-30].”

Discussion (Lines 482-485): “We have based this update of the 2013 guideline on contemporary
evidence-based guidelines [10, 14, 15, 31], scientific evidence from systematic reviews [17-22],
randomised controlled trials [23, 24], observational studies [9, 25-30, 32-34], and expert opinion,
involving experts from eight different disciplines involved in the treatment of people with diabetic foot disease.”

And discussion (lines 491-496): “Compared to the recommendations from the 2013 guidelines, some have not changed, and a number of new ones have been added. These include the need for health professionals to prescribe medical grade footwear that has demonstrated plantar pressure reducing effects at high-risk plantar areas for those people with a healed plantar foot ulcer, to review the adequacy of any prescribed footwear every three months, and to treat a plantar foot ulcer primarily with appropriate offloading devices.”

We also further highlight that we have for the first time created a consensus list of definitions for this field in Table 1 that was designed to contextualize the field much better from an Australian and international perspective. Lastly, as per Reviewer 1, point 9, we have added a section on the potential cost savings of introducing such footwear recommendations into the Australian context using recently published Australian cost-effectiveness analysis findings that incorporate prescribing footwear in optimal care.

3. The article's key recommendations while valid, are fairly traditional and would be familiar to the readers.

Response: We thank the reviewer for this comment and we politely agree and disagree with their comment. We agree that many recommendations have remained similar to the recommendations from the 2013 guidelines. However, we see this as a strong point of the guideline. It would be rather surprising if an updated guideline would bring a suite of entirely new recommendations to any field.

This is also evident in the IWGDF guidelines that consist of recommendations from previous iterations (as no new or contradicting literature had been published) and new recommendations (from new or contradicting literature published since the last guideline). We also highlight that the IWGDF guidelines are updated every 4 years and the NHMRC guidelines are recommended to be reviewed within 5 years (although they haven’t been since 2011 unfortunately). Therefore, our update of the 2013 guidelines in 2017 meets the international standard for diabetic foot guidelines.

However, we disagree with the reviewer’s comment that all key recommendations are fairly traditional and familiar “to the readers”. As per our comment to address the reviewers point above, we have introduced several new recommendations in this 2017 guideline that weren’t made in the 2013 guideline. This is because several pivotal RCTS have been published since 2013, along with aforementioned systematic reviews and guidelines. We have now taken the opportunity to specifically highlight these new recommendations in the Discussion (Lines 491-496):

“Compared to the recommendations from the 2013 guidelines, some have not changed, and a number of new ones have been added. These include the need for health professionals to prescribe medical grade footwear that has demonstrated plantar pressure reducing effects at high-
risk plantar areas for those people with a healed plantar foot ulcer, to review the adequacy of any prescribed footwear every three months, and to treat a plantar foot ulcer primarily with appropriate offloading devices.”

We also believe these recommendations are not familiar or enacted by the vast majority of health professionals that manage diabetic foot disease in Australia as evidenced by not being included in the 2013 footwear guideline and our inability to find any literature in Australia investigating the prescription of plantar pressure reducing medical grade footwear.

While we would love to believe that the majority of health professionals are aware of the literature, our experience has taught us that this is not the case. This guideline serves as a document to combine all the knowledge that is already out there in this field in one document: to serve every health professional working with this population, to provide recommendations to these health professionals, and to provide them with a document that they can use to show others (outside the field) why they are doing what they are doing is based on best evidence.

4. Please consider including in the recommendations, that patients "wear-in" new footwear gradually. This is frequently given (and safe) advice from experienced clinicians and providers. In my view, this is at least as important as the recommendation provided that patients wear socks with footwear (as stated by the authors).

Response: We thank the reviewer for this valid point, and have added this to the rationale and to the considerations on footwear provision (Lines 201-204):

“When new footwear is provided to a person with diabetes at low-risk of foot ulceration, advise them that a “wear-in” period may be needed where they slowly increase the number of hours per day the footwear is used, and that they should be extra vigilant of their foot health in this period.”

5. I agree there is stronger evidence with regards to ulcer prevention when there is adherence to wearing of custom, medical grade footwear (23). However, Australia has few appropriately trained custom shoe makers (one of the Authors being one) and Australia does not have a National, universally available public funding scheme to support the provision of footwear for people with diabetes who need them. The majority of medical-grade footwear provided in Australia to patients with diabetic foot complications and deformity is off-the-shelf +/- modifications and relatively fewer patients are prescribed custom-made footwear. I don't know if the authors agree with this or not but I believe that this should be addressed in the article and some guidance with regards to custom versus off-the-shelf footwear provided.

Response: We thank the reviewer for this comment, however, we were a little confused by it, as there are no recommendations in the guideline that specifically recommend custom-made footwear. Recommendations 7 and 8 concern “medical grade footwear”, which refers to both prefabricated and custom-made medical grade footwear, as defined in Table 1.
As the reviewer rightly acknowledges, the majority of medical grade footwear provided in Australia is prefabricated (extra-depth or width) footwear with or without modifications. Such footwear can still be in line with our recommendation for people with a healed plantar foot ulcer, provided the health practitioner can demonstrate it reduces plantar pressure. Such a demonstration is not limited to pedorthists, but can easily be done by a podiatrist, medical practitioner or similar health professional.

We agree though that the debate around “prefabricated vs. custom-made” can be complex one. However, the goal is to provide a person with diabetes with appropriate footwear, with demonstrated plantar pressure reduction, adequate length, width and depth, and adequate accommodation of foot deformities. The type of medical-grade footwear needed to achieve this depends on the individual foot, and the measurements the health professional has taken. We recommend and have advocated in our guideline that a health professional should demonstrate that the footwear is appropriate. Such demonstration means that we should now “demonstrate that your treatment works”.

6. In marrying recommendations to the NHMRC endorsed risk stratification, the point of difference between the different recommendations for people (at risk) with deformity and (at risk) without foot deformity becomes somewhat lost. How to determine who needs regular, medical-grade or Custom Medical Grade should be clearer.

Response: We agree that the NHMRC risk stratification is somewhat unclear to meet all the aims of this paper, as people with and without foot deformity can have the same risk status, while they have different footwear needs. However, unfortunately no risk stratification that we are aware of specifically deals with specific foot deformities (the IWGDF does not either), but these risk stratifications are important as a first layer to separate between low-risk vs intermediate- and high-risk.

We politely disagree though that how to determine who needs regular or medical-grade footwear is not explicitly stated in each recommendation. Each recommendation starts with a description of the specific population for whom that recommendations accounts (e.g.: “Motivate people with diabetes at intermediate- or high-risk of foot ulceration”; “For people with a foot deformity, pre-ulcerative lesion or healed non-plantar foot ulcer, consider prescribing […]”; “For people with a healed plantar foot ulcer, prescribe […]”). That order is chosen, since footwear prescription starts with a risk assessment. That risk assessment will make clear which recommendations account for that person, and from that the need for regular or medical-grade footwear follows.

7. This new version does not differ from the original 2013 guidance in this key recommendation but it is harder to find the recommendation in the 2017 text. This 2017 version states on line 207 “When a foot deformity or pre-ulcerative lesion is present, consider prescribing medical grade footwear which may include custom-made in-shoe orthoses or insoles.”

The 2013 article says the same in a table.
Response: We thank the reviewer for these valuable comments and we have taken this opportunity to more clearly state each recommendation now in 3 different areas of the manuscript, both separately and together in the Abstract, Results and in a new summary table (Table 2).

With regard to the specific 2013 recommendation compared to similar 2017 recommendation the reviewer refers too: whilst we have made only minor changes, we are sure the reviewer would appreciate these subtle differences on closer examination.

For instance, the 2013 recommendation stated: for a “High (risk) … abnormal foot shape, including history of amputation … Medical grade footwear and custom moulded foot orthoses will generally be required… Foot orthoses to be supplied prior or together with prescribed footwear.”.

Whereas, the 2017 recommendation states: “footwear for people with diabetes at intermediate- or high-risk of foot ulceration: (7) For people with a foot deformity or pre-ulcerative lesion, consider prescribing medical grade footwear, which may include custom-made in-shoe orthoses or insoles”

Whilst similarities are apparent, the 2017 recommendation has broadened to incorporate the technically correct definition of intermediate and high-risk as defined by NHRMC guidelines and importantly includes and defines pre-ulcerative lesions (e.g. callus, corns, blisters) which was not included in 2013. We furthermore addressed the general reasons for regular updates of guidelines in points addressed above.

8. Line 221 - Check reference for this statement.

Response: We thank the reviewer for picking up an inadvertent error and we have corrected this reference.

9. The article could be shorter and more concise. Consider placing some of the rationale and discussion about the process and structure elsewhere and not in the main body of the article. This will assist readers to access the information they need. Consider tabulating the key recommendations.

Response: As described above, we have now taken the opportunity to highlight the recommendations clearly in 3 different areas of the manuscript to assist the lay or expert reader, including tabulating the 10 key recommendations. We thank the reviewer for the recommendation to tabulate recommendations as we agree this is much easier for the reader now. Thus, for those who want a very quick view of the key recommendations, all they have to do is read the abstract or Table 2. For interested readers, they can read the rationale, like they do in
other major guidelines. In our opinion, the rationale following the recommendations is relatively
short, with generally just one paragraph per recommendation. We have taken the opportunity to
now also state the related recommendation in front of the rationale explaining the
recommendation throughout the results which also segments the guidelines nicely. We now
believe our submitted manuscript is consistent with international best practice for diabetic foot
disease guidelines as it mirrors the same structure as the IWGDF guidelines. As with any
scientific article, those who are interested even further can go the discussion. By adding
subheadings, people can browse through these topics with ease, to get the information they need.

10. Line 242-3 - Guidance on how to address suitable footwear for indoors would be useful
given knowledge that many patients often don’t wear their prescribed footwear in their home
(30,40)

Response: We thank the reviewer and have added a statement about indoor footwear (Lines 274-
276):

“The indoor footwear should meet the same requirements with regard to adequacy of fit and
offloading, but compromises might be made in the materials used in manufacture, as it is likely
to experience less “wear-and-tear” compared to footwear used outdoor.”

11. Line 259 - Consider that medical grade footwear may be required to accommodate
deformities which cause dorsal foot wounds (eg. Clawed toes) and not just plantar ulcers (as stated).

Response: We thank the reviewer for raising this point. This recommendation is specifically for
people with a healed plantar foot ulcer, as pressure measurements are currently only possible on
the plantar surface. We acknowledge the reviewers valid point, but in the example of clawed
toes, it’s the foot deformity that determines the need for footwear, not the dorsal ulcer. This is
covered in recommendation 7: “For people with a foot deformity or pre-ulcerative lesion,
consider prescribing medical grade footwear, which may include custom-made in-shoe orthoses
or insoles”. In our opinion, when dorsal ulcers are not caused by foot deformities or pre-
ulcerative lesions, they do not need medical-grade footwear. As such, the current
recommendation covers foot deformities that may cause dorsal foot wounds.

12. The inclusion of contemporary data from Arts (25) in Table 4 is not highly applicable. It
relates to a study where changes made to existing custom-made footwear when areas of >
200kPa were identified using in-shoe pressure measurement. It actually raises more questions. I
am not critiquing the original article but questioning the value of providing this table, out of
context, within this article.

Response: We thank the reviewer for their point; however, we have to disagree. We believe
Table 4, adapted from the article by Arts et al, is the first objective attempt to translate the
subjective art of footwear (and insoles) prescription and modification, into objective data-driven
guidance to practitioners on what modifications singularly or in combination are most likely to produce the optimal demonstrated reductions in plantar pressure. This table enables clinicians for the first time in a guideline to finally base their footwear prescription on scientific evidence. In our opinion, tables 3 and 4 are most useful additions, as it’s the first time these are combined and translated into guidance for clinical practice. The article by Arts and colleagues exactly aims for such a translation, so that their valuable information (of probably the best footwear study done so far) gets used, and the field progresses to a data-driven direction.

13. "Replacement of top cover" - Replacement from what material to which new material?
Response: See our response to a minor similar specific point by reviewer 1: we have added “with a new top cover of the same material”.

14. "Addition of medial arch support" What material, height etc?
"Adjustment of pivot" To where? Etc…
Response: We agree that more details, for example in materials, sizes, locations, etc, would translate this even further to clinical practice, but unfortunately such details are outside our scope. As can be seen from the original 2013 guideline, where the information is not provided in either, because it’s not available. Table 4 is an algorithm, it’s not a golden rule, and any intervention should be followed by demonstrated evidence of its effectiveness in reducing plantar pressure.

15. Table 3 from a 2001 article is derived from considerably older reference material on footwear design from the 80's and 90's. Again, I am not critiquing the original article but ask the authors to re-consider the value of this table in the context of this current article. To whom is this information being targeted?
Response: We agree that this is a rather old article, but would like to stress that this has been used in a recent RCT with demonstrated effectiveness (Rizzo et al). We have updated the table from the 2001 article based on the experience of the 14 co-authors, all being Australian and international experts in the field. A separate project to further improve both tables 3 and 4 would of course be even more interesting, but such a project is outside the scope of the current article. We chose not to leave it out, as even our limited approach to translate these tables into algorithms useful for everyday practice in Australia provides a unique guideline with data-driven directions. We combine all contemporary footwear evidence and clinical practice in recommendations and clinical algorithms that are not available in any other document. We
acknowledge that the prescription of orthoses is not specifically covered in the tables, and have added this. Unfortunately, there is no evidence for an algorithm on orthoses prescription.

16. There is some nice discussion regarding the patient perspective and behaviour change at the end which is not covered in the 2013 version and this helps lead us to a more patient-centred approach.

Response: Thank you, that’s great to hear.

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