Preferred Offloading Modalities for Management of Diabetic Foot Ulcers in Private Clinical Settings: A Survey of Australian Podiatrists

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Research Article

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Preferred offloading modalities for management of Diabetic Foot Ulcers in private clinical settings: a survey of Australian Podiatrists

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Diabetic peripheral neuropathy is a common complication of diabetes mellitus. Neuropathy predisposes patients to diabetic foot ulcers (DFU) due to the loss of protective sensation and associated deformities. Management of foot ulcers are multifactorial, but pressure offloading can be considered as one of the most important aspects of management. According to IWGDF Guidelines,
non-removable knee-high offloading devices are recommended as the 1st line of treatment for these ulcers. However, this is a very underutilised treatment modality. This study aimed to evaluate the practitioner preferred offloading modalities and reasons for their preference.

Methods
This project was approved by the university’s human research ethics committee. An online survey was distributed amongst Australian podiatrist via an industry related social media group. The survey collected simple demographical information, management strategies, preferred offloading modalities for the management of diabetic foot ulcers and reasons for their preferred method.

Results
Sixty-three podiatrists completed the survey with the majority practicing in private clinics. All practitioners treat diabetic foot ulcers regularly with most participants treating up to ten ulcer cases per week and 14% of participants treating more than 20 ulcers per week. Contrary to the IWGDF guidelines, standard therapeutic footwear was the most preferred method of management for the treatment of diabetic foot ulcers, with ease of use reported as the main reason for practitioners using this modality. Non-compliance to the use of non-removable knee-high offloading devices include perceived patient non-compliance and poor tolerance.

Conclusion
This study shows that practitioners’ offloading strategies do not adhere to the IWGDF guidelines. The reasons for not adhering to the guidelines seems to be a clinical practicality rather than evidence-based practice. Reasons for choosing a management strategy is multi-factorial (not just reducing plantar pressures). Further studies may be required to evaluate the effectiveness of therapeutic footwear in ulcer healing, taking into consideration other factors such as practitioner and patient preference, clinical practicality, and access to support. Based on the findings, this study provides suggestions on how to overcome the barriers that prevent podiatrist from adhering to the recommendations of the IWGDF when selecting offloading devices in general clinical practice.

Abstract word count: 348
Diabetic peripheral neuropathy (PN) is a common complication of diabetes mellitus, and it is estimated to affect 50% of the diabetic population (1). PN predisposes patients to diabetic foot ulcers (DFU) due to the loss of protective sensation and associated deformities. With the loss of sensation, the individual is unable to feel pain or discomfort associated with excessive skin pressure and shear from foot contact surfaces such as footwear, or the ground. This eventually results in a breakdown of tissue, and finally an ulcer in the high-pressure area (2).

In Australia, a recent systematic review of the incidence of diabetic foot disease noted that the overall incidence of diabetic foot disease is lower (1.5%) when compared with the rest of the world (4.8%). However, the incidence of in-patient admissions due to foot ulceration is much higher than the rest of the world, with diabetes related amputations being the highest amongst developed nations. A conclusion made from this data was that Australia is doing well to prevent DFU but not in managing them once they developed, resulting in high numbers of admissions and amputations due to diabetes related complications (3).

In Australia, podiatrists are one of the key carers for DFUs. Podiatric management of DFUs include sharp debridement of necrotic tissue, timely and appropriate wound dressings application, control of the underlying disease process, footwear modification to off load pressure from the DFU, patient education and self-care (4). Pressure offloading can be considered as one of the most important aspects of DFU prevention and management (5).

Since 2008 the International Working Group on Diabetic Foot (IWGDF) produced evidence-based guidelines to assist with the management of diabetic foot disease and it became the benchmark for clinical practice standards (6). These guidelines are frequently reviewed and updated to include the latest research findings with the latest update in 2019 (7). A section in the IWGDF Guidelines is dedicated to the best practices for offloading of DFU with eight recommendations for the management of DFUs. Non-removable knee-high devices are recommended as the first line of management for
non-infected and ischaemic DFU associated with neuropathy (7). A non-removable knee-high offloading device refers to a Total Contact Cast (TCC) which consists of a close fitting plaster or fiberglass cast covering the foot, extending up the leg and ends just below the knee; or an instant Total Contact Cast (I-TCC) which consists of a prefabricated knee-high walking boot that is rendered irremovable by wrapping the device with a layer of casting material.

TCCs have been considered the gold standard for managing plantar forefoot and midfoot ulcers complicated by neuropathy. The ulcer healing rate using TCCs over a 12-week period was found to be 89.5%, which was significantly higher than the healing rates when using removable walking boots (65%) and post op shoes (58.3%) (8). However, this modality is extremely underutilised in clinical practice. In a study to evaluate the effectiveness of a new wound dressing when used in conjunction with TCCs, Thompson et al (2019) managed to only recruit 13 participants from a population of 270 (4.8%) (9). Another study by Raspovic and Landorf (2014) found that amongst podiatrists working in high-risk foot settings in public hospitals, semi-compressed felt padding was most commonly used for offloading, with TCCs being the third choice (10). Reasons for low utilisation of TCCs were attributed to high cost, time to apply, fear of complications and lack of expertise (plaster technician) to apply the TCC (11, 12).

In Australia, most practising podiatrists do not work in public settings with support for high-risk foot conditions. Examples of these private practice or similar primary care settings include privately owned podiatry clinics, aged care facilities and community clinics. Patients with DFUs will often be managed by podiatrists working in these private and primary care settings. It is not known how patients with DFUs are managed in these settings, specifically if IWGDF guidelines for offloading are adhered to.

As it is not feasible to collect data from every private primary care setting in Australia, the way patients are managed may be inferred from practitioners’ perception. This study aimed to survey the preferred offloading modalities used by Australian podiatrists in non-public high risk foot settings, and reasons for their choices. Practitioners feedback on how treatment provision may be improved was also obtained.

METHOD
This study was a cross sectional study collecting data using an online survey and disseminated through a closed podiatry Facebook group.

**Participants**

The study was approved by the university human research ethics committee (HREC Number: XXX). All participants provided electronic informed consent. The inclusion criteria were that participants must be podiatrists currently registered with the Australian Health Practitioners Registration Agency (AHPRA) and they treat at least 1 patient with DFU per week. They must also not be working in a public hospital high risk foot facility.

**Survey**

The online survey was created via Qualtrics™ (Qualtrics, Provo, UT, USA) and consisted of 13 mainly multiple-choice questions. Some multiple choices questions had an ‘others’ choice which allows participants to fill in free text, where their answers were not part of the list of options. These free text options were evaluated as well. Questions 1-5 gathered data regarding the nature of the podiatrists’ work (e.g. private or public setting, post code etc) and average weekly number of patients seen with DFUs. In Question 6 – 9, participants were asked what modalities they used to treat DFUs (e.g. patient education - verbal or written, sharp debridement, wound care etc) and their reasons. Question 10 – 12 gathered data regarding participants’ offloading preference and reasons. There were four offloading modalities for participants to choose from and these were taken from the IWGDF guidelines namely – non-removable knee-high offloading devices, removable knee-high offloading devices, ankle-high removable devices, and standard therapeutic footwear (7). Question 13 sought participants’ thoughts regarding how DFU management can be improved in a primary care setting. As participants were anticipated to be busy clinicians, the survey was kept short, taking no longer than 15 minutes to complete to encourage participation.

**Statistical Analyses**

Participant data were analysed descriptively and quantitatively. All data was analysed using SPSS v28 (IBM Corp., Armonk, NY, USA).

**RESULTS**

**Participant profile**
A total of 63 complete responses were eligible for final review. Majority of the participants (59%) had five years or less of work experience. 16% had 6 to 10 years of experience and 25% had more than 10 years. 50.8% of participants worked in multiple different clinical settings, ranging from private podiatry clinics, public hospitals, and aged care. 31.7% were working in only private clinics, followed by 11.1% in public hospitals (non high-risk foot specific), 4.8% in community centres and 1.6% in aged care facilities.

**DFU management strategy**

Participants were asked to list any of their management strategies used in treating patients with DFUs. Participants could choose more than one option. Looking at Figure 1, 61 practitioners provide regular podiatric treatment (including wound debridement and dressing) in conjunction with other treatment modalities. Other management include provision of semi-compressed felt padding and strapping, alongside with referrals to their general practitioner or other health professionals, patient education, providing other custom-made offloading devices and specialised wound dressings, as well as referral for radiological investigations.

Review periods varied amongst practitioners with 31.7% reviewing patients once a week, 25.4% reviewed them once a fortnight, 22.2% reviewed them once a month. 14.3% reviewed patients two or more times per week and, 6.4% did not specify their review period.
To evaluate the preferred DFU offloading modality, participants were asked to rank from 1 being their most preferred to 4 being their least preferred offloading choice for DFU. The treatment options included non-removable knee-high offloading device, removable knee-high offloading device, removable ankle high offloading device and standard therapeutic footwear. Results showed that most participants chose standard therapeutic footwear as their first choice, removable knee-high devices as their second choice, removable ankle high devices as their third choice and non-removable knee-high devices as their fourth choice. (Figure 2)
Participants were asked to provide their reasons for their choice particularly their first choice. Table 1 shows the reason selected by the majority of participants for their first choice.

<table>
<thead>
<tr>
<th>First choice</th>
<th>Number of participants</th>
<th>Main reason for choice</th>
<th>Number of participants who chose this reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic footwear</td>
<td>24</td>
<td>Convenient and accessible</td>
<td>17</td>
</tr>
<tr>
<td>Non removable off-loading knee-high devices</td>
<td>17</td>
<td>Effectiveness in healing ulcer</td>
<td>12</td>
</tr>
<tr>
<td>Non removable off-loading knee-high devices</td>
<td>17</td>
<td>Patient satisfaction</td>
<td>10</td>
</tr>
<tr>
<td>Removable off-loading ankle-high devices</td>
<td>5</td>
<td>Patient satisfaction</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Main reasons for selecting preferred offloading choice for management of DFU

Suggestions for improvement

When asked what would be required to improve care for patients with DFUs, 34% felt that more continuing professional education for practitioners to improve and update wound care management
knowledge was necessary. 26% suggested for more high-risk foot facilities to increase accessibility and provide more open communication with multidisciplinary teams and seamless referral pathways for patients with DFU related complications. Finally, 24% wanted improved health funding to support patients with DFU. 16% did not respond to this question.

DISCUSSION

The study found that standard therapeutic footwear in conjunction with regular podiatry treatment was commonly used to treat DFU in a non-high-risk foot setting. This is not in line with IWGDF guidelines that advise that standard therapeutic footwear should only be used when none of the other recommended knee-high offloading devices are available. However, results from this study are consistent with the findings of Wu et al (2008) who reported that 41% of practitioners use shoe modifications as the preferred method for the treatment of DFU over the gold standard TCC (12). In this study, it must be acknowledged that most of the practitioners worked in private non-high risk foot settings, and it can be possible that the DFUs presented may be less severe, and therefore the responses reflect the effective management of less severe plantar ulcers in patients with less comorbidities. It is well documented that there are obvious disparities between the initial presentation of DFU in public settings when compared with private. Patients in public services present with more severe DFU complicated by more significant comorbidities and socioeconomic factors (13). These factors put these patients at a higher risk of complications and ultimate amputation. This study was a survey of practitioner’s preference of management and therefore, actual severity of presenting DFUs and outcomes of care (healing rate) was beyond the scope of the study. Further research to evaluate the effectiveness of the current practices by looking at healing rates and complications in private practice is necessary.

With the increased severity of DFUs seen in public high-risk foot settings, it may be expected that a survey focusing on practitioners in High-risk Foot Services may return a different set of responses. However, a recent survey targeting podiatrists in high-risk foot services in Australia also reported the use of felt padding and therapeutic footwear as the primary treatment choice with non-removal devices as only the 3rd treatment choice (10). This may indicate that regardless of work setting, the results from this survey are realistic and accurate, and reflect the practices of the podiatrists in general.
To understand the rationale behind current practices, this study also collected data regarding the reasons behind the practitioners’ ranking preferences.

Results from this study showed that convenience and accessibility strongly influenced the selection of therapeutic footwear as the first choice of offloading modality. This implies that practitioners may have felt that therapeutic footwear were more convenient and accessible to use. Standard therapeutic footwear such as Darco, can be purchased from specialised shoe shops or ordered from local suppliers, which would naturally make this modality more accessible to both practitioner and patient. In addition, since most practitioners also provided regular wound debridement and dressing, this may necessitate regular inspection and wound dressing changes, which is possible with the use of therapeutic footwear. Furthermore, removable devices are indicated for DFUs in the presence of infection and ischaemia, further supporting the use of removable offloading devices (14).

Brem & Boulton (2004) stated that to effectively implement the use of TCC requires a skilled cast technician and application and removal is a time-consuming process (15). Many private community-based podiatry clinics tend to have a broad scope of practice with a stronger focus on preventative care and less on the active management of diabetic foot complications. Although the total patient weekly load was not asked, the number of patients with DFUs may form a small proportion of total weekly patient volume. As such, it may not be cost effective to employ a plaster technician for the purpose of applying and removing the TCCs, which may reduce the accessibility of TCCs in a regular clinical setting.

Practitioners who selected TCCs as their first choice acknowledged its efficiency in wound healing. This is supported by literature that stated the healing rate for TCC was 90% with a mean time to healing of 42 days compared to 32% and 65 days for the group with cushioned inserts in therapeutic footwear (16). However, an equal number of participants chose removable knee-high devices as non-removable knee-high devices. High quality studies have shown that knee-high removable offloading devices were up to 76% more effective in healing DFU when compared with therapeutic footwear (7). The choice of a removable knee-high device was attributed to patient compliance and satisfaction. Patients may be reluctant to use the non-removable device as this hinders them from their regular activities, and practitioners may be seeking a compromise by using a removable device. Studies have
shown that patients spend 75% of their active time not wearing their prescribed removable offloading device reducing its effectiveness (17). Ironically, the patient's ability to indulge in regular activity and be comfortable, which is seen as positive to the patient, is a hindrance to wound healing. On the contrary, when using non-removable devices, patients cannot remove the device themselves. This is termed ‘forced compliance’ (16). Non-removable devices slow the patient down by reducing stride length and activity, thereby promoting wound healing (8).

To resolve this issue, the use of I-TCC may be suggested. A I-TCC is a removable knee-high boot, that is rendered irremovable by wrapping it with a plaster cast after it has been fitted on the patients' foot. Like therapeutic footwear, the removable knee-high boot is commercially available and does not require a skilled plaster technician to apply and remove. The I-TCC cannot be removed daily by the patient but can be removed by the practitioner for routine wound care. The I-TCC was reported to be as effective as TCCs in offloading and healing plantar ulcers (I-TCC = 94% vs TCC = 93%), cost less than the TCC (I-TCC = US$145 vs TCC = US$811), (11, 12, 18, 19), and also has a significantly lower application time than the TCC (I-TCC = 2 minutes vs TCC = 15 minutes) (18). These results and benefits were further confirmed in the extensive systematic reviews by IWGDF (2019) (7, 18). In addition, in relation to infected wounds, the latest guidelines by IWGDF stated that non-removable devices can benefit the healing of DFU with mild infections (7). I-TCC can play an important role when dealing with infected wounds during early phases of care where the device can be left removable to facilitate frequent wound inspection and monitoring of infections. As soon as the infection stabilised and wound condition improved, the device can be converted to an irremovable device. The introduction of the I-TCC may be a viable way to permit the optimal offloading of plantar ulcers within the constraints of a regular clinical setting. For this to occur, continuing professional education for clinicians is required, and this is supported by the findings of this study when practitioners responded that more continuing education is required to ensure that clinicians remain up to date with wound management research and techniques.

Suggestions for improvements to service

Participants reported 3 areas where service for high-risk foot can be improved, namely, more continuing professional development, increased communication with multi-disciplinary teams and increased funding for chronic DFUs.
Continuing Professional Development (CPD)
Data from this study shown that 59% of practitioners dealing with DFU patients have less than 5 years
working experience. This shows the importance of CPD. The podiatry association and other bodies
specialising in wound care (Advanced Practising High-Risk Foot Group) regularly conduct webinars
and sessions in this area. However, given the burn-out rate of podiatrists (20), including effects of
dealing with the COVID-19 pandemic (21), it may be unrealistic to expect clinicians to undertake
further training beyond that required for podiatry registration.

Communication with High-Risk Foot Teams and increased referral pathway to multidisciplinary
services
Currently most multidisciplinary high-risk foot services are in larger centres that make it inaccessible
to regional and rural patients and communication between clinicians can be limited. Recent COVID-
19 restrictions placed a renewed emphasis on the use of telehealth and telemedicine. Even with
developments in technology, limitations in the accuracy and reliability remain. However, the use of
technologies have shown to be effective in assessing, monitoring, and teaching in the management
of diabetic foot disease (22), which may be useful for more experienced podiatrists to mentor less
experienced ones.
The formation of multi-disciplinary community centres with services such as nursing services to
change wound dressings, diabetes care management and education, radiology, pharmacology, and
potentially plaster casting services may meet the needs of podiatrists and patients alike. These multi-
disciplinary services can provide a one-stop service for patients to access a range of support services
and will serve podiatrists and other allied professionals in private practice within a catchment area.
Patients will be able to have faster and more convenient access to the community service compared
to being referred to a high-risk foot service within the hospital. Further qualitative studies need to be
done to find out a good model of care that is financially viable and meets the clinical needs of all
stakeholders.

Funding
Although not one of the top reasons, high cost of a device was identified as one of the reasons for choosing a modality and the patients’ ability to afford treatment over the long term will influence practitioner’s treatment choices. This results in sub-optimal care placing an economic burden on the patient as well as the health system. The treatment of DFUs was reported to be a significant economic burden on patients and the health care system with an annual expenditure of US$9 – 13 billion in the US. By optimising care with evidence-based principals an annual cost savings of AUD 2.7 billion over 5 years can be generated (23).

Practitioners could educate patients on the concept of cost-effectiveness (higher cost over a short period vs lower costs over a long period), and that evidence-based care will result in better outcomes, be more cost-effective and even result in cost savings (24).

In terms of funding for DFU management, the Australia Government and The National Health & Medical Research Council (NHMRC) do recognise the financial burden of diabetic foot complications and provide funding for best-practice management, which include “TCC or other devices rendered irremovable” via its Medical Benefit Scheme (MBS) (25). When asked what could be improved, many practitioners stated that more funding for DFU management was required. It could be possible that practitioners are not fully aware of how to access these funding schemes for patients to reduce the financial cost of treatment. Incentivising cost-effective evidence-based wound care within MBS and listing evidence-based wound products on MBS will not only ease patients’ financial burden but also save considerable costs for Australia’s health system (23).

**CONCLUSION**

Results from this study showed that standard therapeutic footwear, together with routine podiatric treatment is the preferred management modality of DFUs in private clinical settings. This was contributed to clinical practicality, and patient compliance. Given its popularity, the role of therapeutic footwear and ways to improve its efficacy in ulcer healing requires further investigation. This study highlighted some thoughts as to the reasons behind this practice and suggestions to help steer practitioners and patients towards the IWGDF recommendations. However, practitioner did report that the current practice is effective. This effectiveness may need further investigation in the form of outcome-based studies specific to the management of DFU in a private setting. Future local
guidelines might have to take into consideration that the presentation of DFU in a private setting may be different when compared to public.

Practitioners responded that they would like more specialised multidisciplinary community centres and funding to support optimal wound healing in patients with DFU within private health care settings. This may be a big ask from struggling healthcare systems. Smaller steps can be taken to improve the communication between multidisciplinary teams and practitioners with further development of telehealth services. The result of this study suggests a need for qualitative studies to find out how we can better support practitioners to optimally manage patients with DFUs.

LIST OF ABBREVIATIONS

Ag dressing – Silver dressing
AHPRA - Australian Health Practitioners Registration Agency
CPD – Continuing Professional Development
DFU – Diabetic foot ulcer
HBOT – Hyperbaric Oxygen Therapy
HRFS – High-risk Foot Service
ID – Infectious Disease
IWGDF – International Working Group on Diabetic Foot
I-TCC – Instant Total Contact Cast
MBS - Medical Benefit Scheme
MD Teams – Multidisciplinary Teams
NHMRC - The National Health & Medical Research Council
NPWT – Negative Pressure Wound Therapy
PN – Peripheral neuropathy
TCC – Total Contact Cast

DECLERATIONS

Ethics approval and consent to participate
Ethics approval was obtained from CQUiniversity’s human research ethics committee (HREC Number: XXX)
Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interest

The authors declare that they have no competing interests

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REFERENCES


LIST OF FIGURES

Figure 1: Other management strategies used in the management of DFU

Figure 2: Ranking of offloading devices preferred by practitioners

Table 1: Other management strategies used in the management of DFU