

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

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Research Article

Keywords: Diabetic foot ulcers, neuropathy, management, IWGDF, guidelines, non-removable, offloading, therapeutic footwear, podiatrist, private practice.

Posted Date: December 15th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-1157285/v1>

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1 **TITLE**

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2

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22

23 **ABSTRACT**

24 **Background**

25 Diabetic peripheral neuropathy is a common complication of diabetes mellitus. Neuropathy
26 predisposes patients to diabetic foot ulcers (DFU) due to the loss of protective sensation and
27 associated deformities. Management of foot ulcers are multifactorial, but pressure offloading can be
28 considered as one of the most important aspects of management. According to IWGDF Guidelines,

29 non-removable knee-high offloading devices are recommended as the 1st line of treatment for these
30 ulcers. However, this is a very underutilised treatment modality. This study aimed to evaluate the
31 practitioner preferred offloading modalities and reasons for their preference.

32

33 **Methods**

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

38

39 **Results**

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

47

48 **Conclusion**

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

57

58 Abstract word count: 348

59

60 **KEYWORDS**

61 Diabetic foot ulcers, neuropathy, management, IWGDF, guidelines, non-removable, offloading,
62 therapeutic footwear, podiatrist, private practice.

63

64 **BACKGROUND**

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

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

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

83 Since 2008 the International Working Group on Diabetic Foot (IWGDF) produced evidence-based
84 guidelines to assist with the management of diabetic foot disease and it became the benchmark for
85 clinical practice standards (6). These guidelines are frequently reviewed and updated to include the
86 latest research findings with the latest update in 2019 (7). A section in the IWGDF Guidelines is
87 dedicated to the best practices for offloading of DFU with eight recommendations for the management
88 of DFUs. Non-removable knee-high devices are recommended as the first line of management for

89 non-infected and ischaemic DFU associated with neuropathy (7). A non-removable knee-high
90 offloading device refers to a Total Contact Cast (TCC) which consists of a close fitting plaster or
91 fiberglass cast covering the foot , extending up the leg and ends just below the knee; or an instant
92 Total Contact Cast (I-TCC) which consists of a prefabricated knee-high walking boot that is rendered
93 irremovable by wrapping the device with a layer of casting material.
94 TCCs have been considered the gold standard for managing plantar forefoot and midfoot ulcers
95 complicated by neuropathy. The ulcer healing rate using TCCs over a 12-week period was found to
96 be 89.5%, which was significantly higher than the healing rates when using removable walking boots
97 (65%) and post op shoes (58.3%) (8). However, this modality is extremely underutilised in clinical
98 practice. In a study to evaluate the effectiveness of a new wound dressing when used in conjunction
99 with TCCs, Thompson *et al* (2019) managed to only recruit 13 participants from a population of 270
100 (4.8%)(9). Another study by Raspovic and Landorf (2014) found that amongst podiatrists working in
101 high-risk foot settings in public hospitals, semi-compressed felt padding was most commonly used for
102 offloading, with TCCs being the third choice (10). Reasons for low utilisation of TCCs were attributed
103 to high cost, time to apply, fear of complications and lack of expertise (plaster technician) to apply the
104 TCC (11, 12).

105

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

111

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

117

118 **METHOD**

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

121

122 **Participants**

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

128 **Survey**

129 The online survey was created via Qualtrics™ (Qualtrics, Provo, UT, USA) and consisted of 13 mainly
130 multiple-choice questions. Some multiple choices questions had an 'others' choice which allows
131 participants to fill in free text, where their answers were not part of the list of options. These free text
132 options were evaluated as well. Questions 1-5 gathered data regarding the nature of the podiatrists'
133 work (e.g. private or public setting, post code etc) and average weekly number of patients seen with
134 DFUs. In Question 6 – 9, participants were asked what modalities they used to treat DFUs (e.g.
135 patient education - verbal or written, sharp debridement, wound care etc) and their reasons. Question
136 10 – 12 gathered data regarding participants' offloading preference and reasons. There were four
137 offloading modalities for participants to choose from and these were taken from the IWGDF guidelines
138 namely – non-removable knee-high offloading devices, removable knee-high offloading devices,
139 ankle-high removable devices, and standard therapeutic footwear (7). Question 13 sought
140 participants' thoughts regarding how DFU management can be improved in a primary care setting. As
141 participants were anticipated to be busy clinicians, the survey was kept short, taking no longer than 15
142 minutes to complete to encourage participation.

143 **Statistical Analyses**

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

146

147 **RESULTS**

148 **Participant profile**

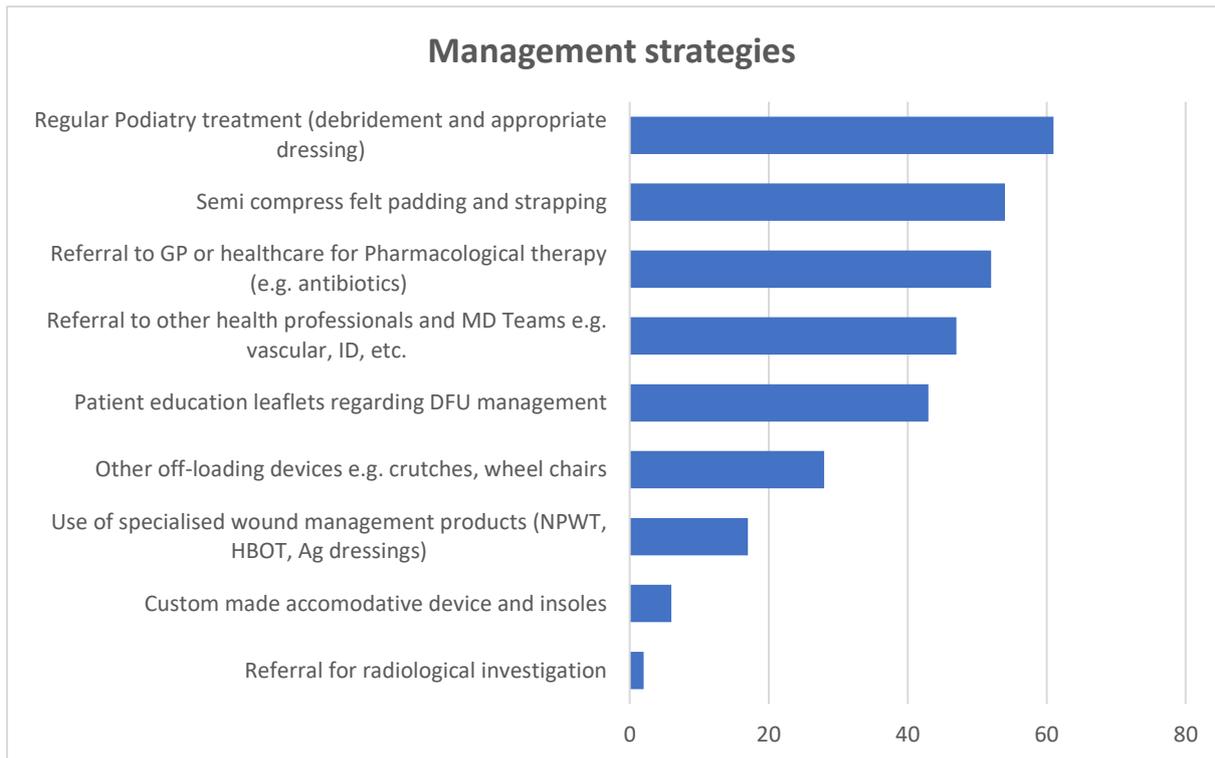
149 A total of 63 complete responses were eligible for final review. Majority of the participants (59%) had
150 five years or less of work experience. 16% had 6 to 10 years of experience and 25% had more than
151 10 years. 50.8% of participants worked in multiple different clinical settings, ranging from private
152 podiatry clinics, public hospitals, and aged care. 31.7% were working in only private clinics, followed
153 by 11.1% in public hospitals (non high-risk foot specific), 4.8% in community centres and 1.6% in
154 aged care facilities.

155

156 **DFU management strategy**

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

164 Review periods varied amongst practitioners with 31.7% reviewing patients once a week, 25.4%
165 reviewed them once a fortnight, 22.2% reviewed them once a month. 14.3% reviewed patients two or
166 more times per week and, 6.4% did not specify their review period.

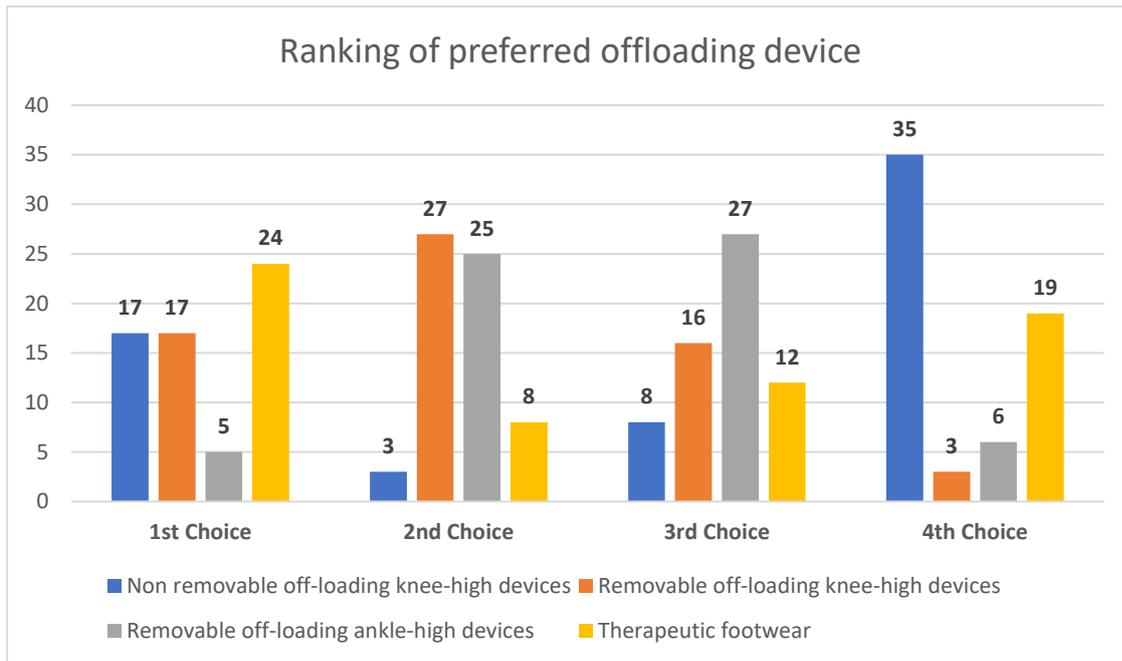


GP - General Practitioner, MD – Multidisciplinary, ID – Infectious Disease, DFU – Diabetic Foot Ulcer, NPWT – Negative Pressure Wound Therapy, HBOT – Hyperbaric Oxygen Therapy, Ag - Silver

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

DFU offloading preference

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)



182

183 **Figure 2:** Ranking of offloading devices preferred by practitioners

184

185 Participants were asked to provide their reasons for their choice particularly their first choice. Table 1

186 shows the reason selected by the majority of participants for their first choice.

187

First choice	Number of participants	Main reason for choice	Number of participants who chose this reason
Therapeutic footwear	24	Convenient and accessible	17
Non removable offloading knee-high devices	17	Effectiveness in healing ulcer	12
Non removable offloading knee-high devices	17	Patient satisfaction	10
Removable offloading ankle-high devices	5	Patient satisfaction	4
Total	63		

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

189

190 **Suggestions for improvement**

191 When asked what would be required to improve care for patients with DFUs, 34% felt that more

192 continuing professional education for practitioners to improve and update wound care management

193 knowledge was necessary. 26% suggested for more high-risk foot facilities to increase accessibility
194 and provide more open communication with multidisciplinary teams and seamless referral pathways
195 for patients with DFU related complications. Finally, 24% wanted improved health funding to support
196 patients with DFU. 16% did not respond to this question.

197

198 **DISCUSSION**

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

216 With the increased severity of DFUs seen in public high-risk foot settings, it may be expected that a
217 survey focussing on practitioners in High-risk Foot Services may return a different set of responses.
218 However, a recent survey targeting podiatrists in high-risk foot services in Australia also reported the
219 use of felt padding and therapeutic footwear as the primary treatment choice with non-removal
220 devices as only the 3rd treatment choice (10). This may indicate that regardless of work setting, the
221 results from this survey are realistic and accurate, and reflect the practices of the podiatrists in
222 general.

223 To understand the rationale behind current practices, this study also collected data regarding the
224 reasons behind the practitioners' ranking preferences.

225

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

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

243

244 Practitioners who selected TCCs as their first choice acknowledged its efficiency in wound healing.
245 This is supported by literature that stated the healing rate for TCC was 90% with a mean time to
246 healing of 42 days compared to 32% and 65 days for the group with cushioned inserts in therapeutic
247 footwear (16). However, an equal number of participants chose removable knee-high devices as non-
248 removable knee-high devices. High quality studies have shown that knee-high removable offloading
249 devices were up to 76% more effective in healing DFU when compared with therapeutic footwear (7).
250 The choice of a removable knee-high device was attributed to patient compliance and satisfaction.
251 Patients may be reluctant to use the non-removable device as this hinders them from their regular
252 activities, and practitioners may be seeking a compromise by using a removable device. Studies have

253 shown that patients spend 75% of their active time not wearing their prescribed removable
254 offloading device reducing its effectiveness (17). Ironically, the patient's ability to indulge in regular
255 activity and be comfortable, which is seen as positive to the patient, is a hindrance to wound healing.
256 On the contrary, when using non-removable devices, patients cannot remove the device themselves.
257 This is termed 'forced compliance' (16). Non-removable devices slow the patient down by reducing
258 stride length and activity, thereby promoting wound healing (8).
259 To resolve this issue, the use of I-TCC may be suggested. A I-TCC is a removable knee-high boot,
260 that is rendered irremovable by wrapping it with a plaster cast after it has been fitted on the patients'
261 foot. Like therapeutic footwear, the removable knee-high boot is commercially available and does not
262 require a skilled plaster technician to apply and remove. The I-TCC cannot be removed daily by the
263 patient but can be removed by the practitioner for routine wound care. The I-TCC was reported to be
264 as effective as TCCs in offloading and healing plantar ulcers (I-TCC = 94% vs TCC = 93%), cost less
265 than the TCC (I-TCC = US\$145 vs TCC = US\$811), (11, 12, 18, 19). and also has a significantly
266 lower application time than the TCC (I-TCC = 2 minutes vs TCC = 15 minutes) (18). These results and
267 benefits were further confirmed in the extensive systematic reviews by IWGDF (2019) (7, 18). In
268 addition, in relation to infected wounds, the latest guidelines by IWGDF stated that non-removable
269 devices can benefit the healing of DFU with mild infections (7). I-TCC can play an important role when
270 dealing with infected wounds during early phases of care where the device can be left removable to
271 facilitate frequent wound inspection and monitoring of infections. As soon as the infection stabilised
272 and wound condition improved, the device can be converted to an irremovable device. The
273 introduction of the I-TCC may be a viable way to permit the optimal offloading of plantar ulcers within
274 the constraints of a regular clinical setting. For this to occur, continuing professional education for
275 clinicians is required, and this is supported by the findings of this study when practitioners responded
276 that more continuing education is required to ensure that clinicians remain up to date with wound
277 management research and techniques.

278

279 **Suggestions for improvements to service**

280 Participants reported 3 areas where service for high-risk foot can be improved, namely, more
281 continuing professional development, increased communication with multi-disciplinary teams and
282 increased funding for chronic DFUs.

283

284 **Continuing Professional Development (CPD)**

285 Data from this study shown that 59% of practitioners dealing with DFU patients have less than 5 years
286 working experience. This shows the importance of CPD. The podiatry association and other bodies
287 specialising in wound care (Advanced Practising High-Risk Foot Group) regularly conduct webinars
288 and sessions in this area. However, given the burn-out rate of podiatrists (20), including effects of
289 dealing with the COVID-19 pandemic (21), it may be unrealistic to expect clinicians to undertake
290 further training beyond that required for podiatry registration.

291

292 **Communication with High-Risk Foot Teams and increased referral pathway to multidisciplinary**
293 **services**

294 Currently most multidisciplinary high-risk foot services are in larger centres that make it inaccessible
295 to regional and rural patients and communication between clinicians can be limited. Recent COVID -
296 19 restrictions placed a renewed emphasis on the use of telehealth and telemedicine. Even with
297 developments in technology, limitations in the accuracy and reliability remain. However, the use of
298 technologies have shown to be effective in assessing, monitoring, and teaching in the management
299 of diabetic foot disease (22), which may be useful for more experienced podiatrists to mentor less
300 experienced ones.

301 The formation of multi-disciplinary community centres with services such as nursing services to
302 change wound dressings, diabetes care management and education, radiology, pharmacology, and
303 potentially plaster casting services may meet the needs of podiatrists and patients alike. These multi-
304 disciplinary services can provide a one-stop service for patients to access a range of support services
305 and will serve podiatrists and other allied professionals in private practice within a catchment area.
306 Patients will be able to have faster and more convenient access to the community service compared
307 to being referred to a high-risk foot service within the hospital. Further qualitative studies need to be
308 done to find out a good model of care that is financially viable and meets the clinical needs of all
309 stakeholders.

310

311 **Funding**

312 Although not one of the top reasons, high cost of a device was identified as one of the reasons for
313 choosing a modality and the patients' ability to afford treatment over the long term will influence
314 practitioner's treatment choices. This results in sub-optimal care placing an economic burden on the
315 patient as well as the health system. The treatment of DFUs was reported to be a significant
316 economic burden on patients and the health care system with an annual expenditure of US\$9 – 13
317 billion in the US. By optimising care with evidence-based principals an annual cost savings of AUD
318 2.7 billion over 5 years can be generated (23).

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

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

331

332 **CONCLUSION**

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

341 guidelines might have to take into consideration that the presentation of DFU in a private setting may
342 be different when compared to public.

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

349

350 **LIST OF ABBREVIATIONS**

351 Ag dressing – Silver dressing

352 AHPRA - Australian Health Practitioners Registration Agency

353 CPD – Continuing Professional Development

354 DFU – Diabetic foot ulcer

355 HBOT – Hyperbaric Oxygen Therapy

356 HRFS – High-risk Foot Service

357 ID – Infectious Disease

358 IWGDF – International Working Group on Diabetic Foot

359 I-TCC – Instant Total Contact Cast

360 MBS - Medical Benefit Scheme

361 MD Teams – Multidisciplinary Teams

362 NHMRC - The National Health & Medical Research Council

363 NPWT – Negative Pressure Wound Therapy

364 PN – Peripheral neuropathy

365 TCC – Total Contact Cast

366

367 **DECLERATIONS**

368 **Ethics approval and consent to participate**

369 Ethics approval was obtained from CQUniveristy's human research ethics committee (HREC Number:

370 XXX)

371

372 **Consent for publication**

373 Not applicable

374

375 **Availability of data and materials**

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

378

379 **Competing interest**

380 The authors declare that they have no competing interests

381

382 **Funding**

383 This work was not supported by any research funding

384

385 **Acknowledgements**

386 Facebook Group: Bridge the Gap for distributing the survey on their social media page.

387 Australian Podiatrist that contributed by responding to the survey.

388

389

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454 **LIST OF FIGURES**

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

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457 Figure 2: Ranking of offloading devices preferred by practitioners

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

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