A surprising patient-led pressure redistribution modality in the treatment of diabetic foot ulceration in Cambodia

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Despite the advances in pressure-redistribution modalities, diabetic foot ulceration is an ongoing global concern, partly due to the unavailability or unsuitability of gold standard treatments. This case report describes a patient-led pressure redistribution device fabricated from a 10 mm ethylene vinyl acetate 'flip flop', which shows potential in aiding reduction in surface area of the wound. Consideration is given to whether this could be used in other resource-poor settings in the treatment of diabetic foot ulceration in the majority world.

Diabetic foot ulceration (DFU) is a well-reported complication of diabetes and has serious life-threatening consequences if not treated effectively (Morbach et al, 2012; Jeffcoate et al, 2018; International Diabetes Federation [IDF], 2019). Published data estimating the extent of diabetes in the Kingdom of Cambodia, a lower middle-income country in the Western Pacific Region, suggests a prevalence of 5.9% (World Health Organization, 2016). The development of diabetic foot services in Cambodia is at an early stage and some of the challenges and opportunities faced by clinicians working in this culture have been previously reported (Hunt, 2019).

Pressure-redistribution strategies have long been at the forefront of DFU management and total contact casting (TCC) has been identified in many guidelines as the gold standard (National Institute for Health and Care Excellence [NICE], 2015; Health Quality Ontario, 2017; American Diabetes Association, 2018; International Working Group on the Diabetic Foot [IWGDF], 2019). Despite these recommendations, the use of TCC is underutilised for a variety of reasons (Wu et al, 2008; Abdul Hadi et al, 2018). Removable cast walkers (RCW) are suggested as the second tier of pressure-redistribution devices (IWGDF, 2019), however, some studies show RCWs as effective as TCCs when rendered irremovable (Armstrong et al, 2005). One of the reported benefits of RCWs is that they are simple and safe to use and do not need the extensive training of clinicians that TCC application requires (Faglia et al, 2010). Other pressure-redistribution modalities have little evidence of aiding DFU healing and are only recommended if TCCs and RCWs are unsuitable or unavailable (IWGDF, 2019).

For many patients in the majority (or developing) world TCCs and RCWs are either unavailable or prohibitively expensive; therefore, several clinicians have sought alternative pressure-redistribution solutions (Miyan et al, 2013; Shankhdhar et al, 2016; Jain et al, 2020). Although some concepts are promising, they lack the vigour of extensive in-depth randomised clinical trials to validate their effectiveness.

In September 2019, after many months of treatment, Patient A attended the Diabetic Foot Ulcer clinic at the Cambodia-Korea Diabetes Centre in the Cambodia-China Friendship Hospital, Phnom Penh, with a self-fabricated pressure-redistribution device. It was simply constructed from a standard 'flip flop' sandal with an aperture cut out to deflect pressure from the perimeter of the plantar wound on

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Figure 1. The 1st self-fabricated pressure redistribution device

his 1st metatarsal head and fitted into his stock 'running shoe' *Figure 1*. This novel method leads to an 84.5% decrease in wound surface area (SA) in 21 days.

Patient details

Patient A was 63 in June 2018. He had been diagnosed with Type 2 diabetes in 2007 and reported that he had had his DFU for 12 months prior the initial appointment. Despite Patient A's long duration of diabetes, the available HbA1c results and the one recorded diastolic blood pressure (DBP) result indicated that his glucose control and DBP is well within the recommended IFD targets (IFD, 2017). A slightly reduced estimated glomerular filtration rate (eGFR) and an elevated blood urea nitrogen (BUN) level suggested an element of mild renal disease *[Table 1]*. His height,174 cm, and his weight, 100.3 kg, resulted in a body mass index [BMI] of 33.1.

Patient A was unable to provide an accurate list of the medication he was taking at that time. He presented with a neuropathic plantar ulcer on the right 1st metatarsal head area, SA 25mm by 15mm (375 mm^2). It was recorded as University of Texas classification B2, indicating that the DFU was down to the tendon or capsule with accompanying infection (Armstrong et al, 1998). The patient reported two other ulcer sites (left plantar metatarsal area and right 4th apex), which had remained in remission.

Table 1. Known test results (* indicates out with normal range)

Test	Result (Date recorded)
HbA1c (%)	6.9 (26/3/2019) 5.4 (22/10/2019) 6.1 (2/1/20)
Diastolic Blood Pressure mmHg	(26/3/2019) 129/66
Complete Blood Count	(26/3/2019)
Hb g/dL (12.5–17.5)	11.1*
Hct % (40.7–50.3)	35*
WBC 1000/mm^3 (4–10)	6.95
PMN % (55–75)	62
LYMH % (20–35)	27
MONO % (2–6)	10*
EOS % (1-3)	1
Platelet 1000/mm^3 (140–400)	270
MCV fL (80–97)	89.9
Lipid Profile	(26/3/2019)
Cholesterol mg/dL (150–200)	110*
Triglyceride mg/dL (<150)	70
HDL Cholesterol mg/dL (>40)	30*
LDL Cholesterol mg/dL (<100)	61
Kidney Function Test	(26/3/2019)
BUN mg/dL (5–23)	30*
Creatinine mg/dL (0.3–1.3)	1.3
eGFR ml/min/1.73 m^2	59.26

DFU treatment history

Patient A's initial assessment and treatment included extensive sharp debridement, 10% povidone-iodine solution on standard gauze and pressure management with a Samadhan offloading device secured with a bandage (Shankhdhar et al, 2016). He was advised to attend a private orthotics company for the fabrication of a total contact insole (TCI) to redistribute plantar pressures from the wound site and he was advised to wear a 'running style' shoe with laces.

By the end of July 2018, a TCI had been fitted but it was not supportive enough for Patient A's body weight and it showed early signs of deterioration even within supportive footwear. Standardised treatment (sharp debridement and 10% povidone-iodine with gauze) continued for several months with minor additions of deflective padding to the existing TCI to attempt to redistribute plantar pressures.

A notable reduction in SA firstly occurred between June and August 2018, following his introduction to an expatriate clinician with extensive experience in treating DFU. A further reduction in SA followed in February 2019, when Patient A reduced his activity levels after complaining of his right limb swelling after exercise; this also prompted a trip to a private hospital in Bangkok, Thailand for further assessment. The reduction in SA encouraged Patient A to further rest his foot in line with the advice he was being given. The expatriate clinician returned to his passport country between April and August 2019 and Patient A did not attend until September 2019.

Figure 2 shows that there was a significant reduction of DFU surface area in October 2019, following Patient A's innovative fitting of the 10 mm ethylene vinyl acetate (EVA) 'flip flop' footwear with an aperture following the circumference of the DFU.

Patient A did not attend the clinic in December 2019. When contacted and asked to attend for a review appointment, his DFU had increased in size and he had manufactured a second pressure-redistribution device and obtained some new footwear *[Figures 3 and 4]*. At his subsequent visit, Patient A informed staff that he was planning a visit abroad with his family. This was advised against but, if he insisted on travelling, he was strongly advised to keep his activity levels to a minimum. Following this trip at the end of January 2020, the SA was 225 mm^2 and there was evidence of severe osteomyelitis (University of Texas grade B3). Patient A refused to be admitted to hospital and ignored the advice and prognosis of the clinicians. He has since failed to attend any follow-up appointment.

Discussion

This case report illustrates the need for alternative pressure-redistribution modalities for the treatment of DFU in resource-poor settings; however, it does also raise some important issues regarding concordance and patient engagement.

On two occasions in Patients A's treatment history, there has been an indication of localised infection (at the initial assessment and in February 2019). Unfortunately, the relationship between antibiotic use and the Cambodian patient is a complex one. The IWGDF Infection Guideline (2019) recommends diagnosing soft

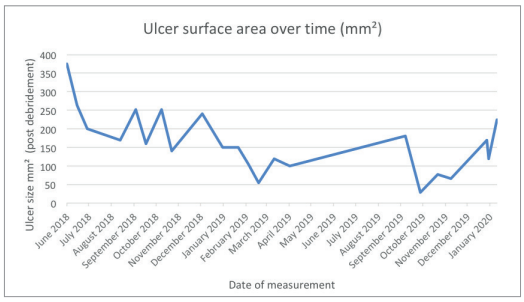

Figure 2. Ulcer surface area over time

Figure 3. The ulcer post debridement (6/01/20)

Figure 4. The 2nd self-fabricated pressure-redistribution device

tissue infection, clinically aided by a collection of a specimen (by curettage or biopsy) to determine the causative pathogen(s). These invasive tests are not routinely undertaken in Cambodia and even the collection of a superficial wound swab is a rare event due to the extra expense for the patient and a five to seven day wait period for results. This highlights the need for clinicians in resource-poor settings to have a high level of skill in reading the clinical signs of infection where other diagnostic tools are not readily available. Furthermore, antimicrobial resistance is a great concern for the Cambodian medical community and many patients will regularly attend 'invisible medicine sellers' or unregulated pharmacists and receive a cocktail of antimicrobial treatments (Suy et al, 2019). Patient A was given clear verbal and written advice on how to cleanse and re-dress his DFU at home. He often attended without a dressing in situ, although he did report daily self-wound dressing. Cambodian attitudes to hygiene prioritise orderliness over cleanliness and many patients do not have a basic understanding of infection-control principles (Overson and Trankell, 2010a).

The standardized treatment provided at the Cambodia-Korea Diabetes Centre for the majority of DFUs is sharp debridement, 10% povidone-iodine with sterile gauze. Sharp debridement is chosen above other forms of debridement due to its speed, simplicity and availability (Lázaro Martínez et al, 2019; IWGDF, 2019) and 10% povidone-iodine is widely used in the Western Pacific Region for its cost-effectiveness and broad-spectrum antiseptic qualities (Bigliardi et al, 2017). Although the latest IWGDF guidelines (2019) recommend a sucrose-octasulfate impregnated dressing for the treatment of neuro-ischaemic DFUs; these are not yet available in Cambodia and would be prohibitively expensive for the hospital to provide.

It is interesting to note that two previous attempts at pressure-redistribution were not effective or upheld by Patient A, despite some evidence for their effectiveness. The Samadhan method of pressure-redistribution has been used in parts of India for more than a decade (Shankhdhar, et al, 2008; Shankhdhar et al, 2016), however, in this clinical setting there has been little uptake for its use as many patients either do not understand the concept of reusing the foam cushion or they find it too bulky to fit in their footwear. There may be some confusion or lack of understanding of the principles of the device as often an expatriate clinician is trying to communicate complex treatment regimes in a second language (Gasiorek and Van de Poel, 2018). Furthermore, although some local staff have completed training on pressure-redistribution concepts from teams in Japan, South Korea and Thailand, it is still not yet widely practiced (primarily due to the lack of resources available) and there seems to be some resistance or lack of confidence in promoting un-known devices or concepts. Patient A was advised to attend a private orthotics company for the fabrication of a TCI with an aperture/depression to redistribute the pressure from the DFU. Although this is not a current first-line treatment advised by International guidelines, it was thought that local prosthetists and orthotists would have sufficient experience of fabricating TCIs for the treatment of DFU. Unfortunately, the TCI that was provided did not provide enough support and the material quickly deteriorated. This may have been exacerbated by Patient A not routinely wearing socks in a tropical environment, which may have accelerated the deterioration of the materials used. Despite encouragement to have a second pair of improved TCIs made, Patient A declined, probably due to the expenses accrued.

The reasons that led to Patient A to fabricate this pressure-redistribution device are unknown; perhaps he had lost faith in those who were providing care for him or perhaps he had grasped some of the concepts of pressure-redistribution from the advice he was being given and decided to 'have a go' himself. Typically within Cambodian society, there is a higher value placed on expatriate clinician care (demonstrated by Patient A's reluctance to attend the clinic when the expatriate clinician was out of the country between April and August 2019) as there is a perception that these clinicians are educated to a higher level. Conversely, Cambodian attitudes to 'Western healthcare' can sometimes be sceptical and if immediate improvements are not experienced, patients are quick to seek alternative treatment from traditional medicine or traditional healers (Overson and Trankell, 2010b). Interestingly, when Patient A travelled to a private hospital in Bangkok in March 2019 to investigate his swollen leg, there was no mention of the DFU in the medical records. The admission sheet notes a queried deep vein thrombosis but there were no record of a duplex venous ultrasound in the

records. Perhaps Patient A did not consider his current DFU as relevant and did not mention it to the Thai clinical staff or it may have been lost in translation.

A recent case report by Bullen and Young (2019) highlighted several factors pertinent to this case including the importance of patient concordance, optimum regularity of debridement and assessment of infection. Although the case report presented by Bullen and Young (2019) was undertaken at a centre of excellence in a developed country there are many similarities to the case of Patient A, e.g unregulated activity against advice, less frequent debridement than would be optimum and frequent evidence of poor wound self-management. This emphasizes that poor concordance and patient engagement is not solely an issue in less developed societies or medical services. Indeed, every effort must be made to build trust and continually educate patients with a DFU about the importance of regular expert assessment and treatment ensuring ownership of their DFU and partnership with the medical professional. This trust has not been fully achieved between the clinical staff at the Cambodia-Korea Diabetes Centre and Patient A, and essentially, and the clinicians involved are aware that progress is needed in this area.

Issues surrounding 'low health literacy' may also be significant to this case report. Previous qualitative research amongst a Cambodian immigrant community in the US highlighted a low health literacy in their sample group; patients typically had poor glycaemic control and demonstrated a poor understanding of their disease (Renfrew et al, 2013). Recent research in health literacy on sodium restriction in Cambodian patients with hypertension highlighted similar findings (Suon and Ruaisungnoen, 2019); this may help to explain Patient A's attitude towards the clear guidance from staff regarding his activity levels, however, this is not necessarily limited to patients in resource-poor settings (Bullen and Young, 2016).

Despite not achieving a positive outcome in this case report, it is worth considering if this pressure-redistribution modality has future potential in this and other resource-poor settings in the treatment of DFU as this option could easily be replicated and used widely for the benefit of many patients.

Understandably, there is no evidence in the literature to support the use of 'flip flop' footwear in the treatment of DFU; there is, however, an understanding that 'flip flop' footwear is widely used by patients with diabetes in similar populations (Isip et al, 2016). Literature considering the biomechanical effects of 'flip flop' footwear use in non-diabetic populations does not support their use (Zhang et al, 2013; Price et al, 2014). However, the biomechanical data within the literature can be largely disregarded in this case report as the EVA material was being used for deflection within a standardised 'running shoe' which provides increased structural support and utilises laces as a retaining medium.

The Shore hardness of the materials used in the various 'flip flop' footwear is not known, however, 40-degree Shore C EVA is typically used in the manufacture of simple 'flip flop' footwear. Jain (2017) noted issues of EVA material 'bottoming out' over time and historically paired 4 mm EVA with 3 mm microcellular rubber (MCR) to counteract this in his 'Amit Jain Offloading System'. Jain has since published a pilot study comparing an EVA/MCR 8 mm combination with 10 mm EVA versions of his device which showed no significant difference in healing times (Jain et al, 2020). Arguably the 10 mm EVA 'flip flop' used would not 'bottom out' in the time taken to allow full-thickness epithelialization and, if the material started to show signs of wear, could be easily and cost-effectively replaced.

As a simple pressure-redistributing modality in the treatment of DFU in a resource-poor setting, the author believes there is potential for future use with some caveats:

- **Patient selection.** This is important as regular clinical assessment, concordance and health literacy are all a factor in this case report.
- **Footwear.** Footwear must be fully enclosed, have sufficient depth and have a suitable retaining medium (laces or hook and loop fastening). This is a potential barrier as cultural and economic factors may prohibit the use of suitable footwear for many in resource-poor settings.
- **Location of DFU.** This method of pressure redistribution would be most suitable for DFU on the plantar metatarsal head area.
- **Trust.** A good relationship between patient and clinician.

Despite these potential barriers, the use of simply modified EVA 'flip flop' footwear could be used for pressure redistribution in the treatment of DFU and can be considered in the future for carefully selected patients.

Conclusions and recommendations

As seen in this case report, the treatment of DFU in resource-poor settings is arguably more complex than in other resource-rich countries.

Ethical principles

Written consent was gained from Patient A and his anonymity was ensured. No ethical approval was required from the National Ethics Committee for Health Research in Cambodia.

The reduced availability and suitability of traditional evidence-based, gold standard pressure redistribution modalities have identified a possible alternative option in the treatment of DFU. Although less than ideal, the use of simple EVA 'flip flop' footwear adapted into pressure redistribution devices could potentially be used widely with limited risk in carefully selected patients and the author would recommend other clinicians to replicate this and share their results.

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Conflict of interest statement

Alastair Hunt has no conflict of interests in relation to this case report and wishes to thank Dr Simon Collins (OMF Cambodia Field Medical Advisor) for his comments regarding this case report.