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Factors associated with adherence to using removable cast walker treatment among patients with diabetes-related foot ulcers

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ABSTRACT

Introduction Adherence to using knee-high offloading treatment is critical for healing diabetes-related foot ulcers (DFUs). However, few studies have investigated patients' adherence to using knee-high offloading treatment. We aimed to investigate the levels and factors associated with adherence to using knee-high removable cast walker (RCW) treatment among patients with DFUs.

Research design and methods In this multicenter cross-sectional study, we investigated adherence to using knee-high RCWs in 57 participants with DFUs. All participants were clinically examined for multiple sociodemographic, physiological, and psychosocial factors. Each participant's adherence level to using RCWs was then objectively measured using dual activity monitors (attached to the wrist and RCW) over a 1-week period. Multiple linear regression was undertaken to determine those factors independently associated with adherence levels.

Results The mean adherence level to using RCWs was 33.6% (SD 16.5) of weight-bearing activity. Factors independently associated with lower adherence levels were being male, longer diabetes duration, not having peripheral artery disease (PAD), and having higher perceived RCW heaviness ($p \leq 0.05$). No associations were found with psychosocial factors.

Conclusions Patients with DFUs adhered to using their RCWs on average for only a third of their prescribed weight-bearing treatment duration. Factors linked to lower RCW adherence levels were being male, longer diabetes duration, not having PAD, and perceived heavier RCWs. These findings highlight the importance of using gold standard non-removable knee-high offloading device treatment. Furthermore, these findings suggest, when gold standard devices are contraindicated, that these factors be considered when prescribing the second choice RCW offloading treatment to optimise adherence. Regardless, further longitudinal studies are needed to confirm these factors.

Significance of this study

What is already known about this subject?

- Adherence to using offloading treatment is crucial for healing diabetes-related foot ulcers (DFUs).

What are the new findings?

- We found people with DFUs adhered to using removable cast walker (RCW) for a third of their treatment.
- We found factors including being male, having longer diabetes duration, not having peripheral artery disease, and perceived heavier RCW were significantly associated with lower adherence to using RCWs.
- We did not find significant associations between psychosocial variables (eg, beliefs or self-efficacy) and adherence to using RCWs.

How might these results change the focus of research or clinical practice?

- Factors found associated with RCW adherence should guide future research and practice.

INTRODUCTION

Diabetes-related foot ulcers (DFUs) affect around 20 million people each year.[1] People with DFUs are at high risk of hospitalization, amputation, and mortality.[1 2] The most common cause of DFUs is high plantar pressure in people with a loss of protective sensation from peripheral neuropathy.[3] Thus, using pressure offloading treatments to reduce the high plantar pressure that causes, and prolongs DFUs, is critical to healing DFUs and preventing hospitalization and amputation.[4]

The gold-standard offloading treatment to heal people with DFUs is non-removable knee-high offloading devices, such as custom-made total contact casts or prefabricated removable cast walkers made irremovable (known as 'instant TCCs').[4 5] Yet, non-removable knee-high offloading devices are contraindicated in patients with both mild infection and mild ischemia, or moderate infection or moderate ischemia, and have been further found to be infrequently used in clinical practice due to several challenges.[5] These challenges include those faced by clinicians in prescribing these

non-removable knee-high devices, such as the increased expertise, time and costs needed to apply, and those faced by patients in tolerating using these devices, such as challenges with driving, bathing, and sleeping.[5]

Removable cast walkers (RCWs) are removable knee-high offloading devices that have been found to reduce the same amounts of high plantar pressure as non-removable knee-high offloading devices but pose fewer contraindications and tolerance challenges to prescribe and use.[4 5] However, despite possessing similar offloading capabilities, RCWs have been consistently found to be significantly inferior to non-removable knee-high offloading devices in terms of healing, and thus, are recommended as the second choice of offloading treatment when patients are contraindicated or cannot tolerate non-removable knee-high devices.[5] The main difference between these devices is the ability for the patient to remove the device and choose to adhere to treatment, and thus, patient adherence to using these devices has a large impact on healing.[4–6] Therefore, understanding the factors that influence patients' adherence to using RCWs seems vital to improving the use and effectiveness of offloading treatments and the healing outcomes for people with DFUs.

To the best of our knowledge, only one previous quantitative study has investigated factors associated with using RCWs in people with DFUs. In that study, factors related to neuropathy severity and DFU severity were found to predict adherence in the USA and UK, but the study found no association with psychosocial factors.[6] However, psychosocial-related factors, such as beliefs, knowledge, and self-efficacy, have been identified to heavily influence treatment adherence in many other conditions[7] and also RCW adherence in previous qualitative research.[8–10] Thus, this study aimed to investigate the levels and factors, including psychosocial-related factors, associated with adherence to using RCW treatment among patients with DFUs.

RESEARCH DESIGN AND METHODS

Study design and settings

This study was a multicenter, cross-sectional study design conducted in three large referral diabetic foot clinics in Jordan: (i) the National Centre for Diabetes, Endocrinology, and Genetics (NCDEG); (ii) Jordanian Royal Medical Services (JRMS); and (iii) Prince Hamza Hospital (PHH). Ethical approval was granted for this study by the Office of Research Ethics and Integrity at the Queensland University of Technology (QUT), Australia (Approval No.1900000418) and each of the Institutional Review Board Committees at the NCDEG (No.3266-9), JRMS (No.T/F3/1-12689), and PHH (No.MH/32/2527).

Participants

Eligible participants were adults who had been diagnosed with diabetes (type 1 or 2), a forefoot or midfoot plantar DFU and had been treated with an RCW by their treating clinician for at least 4 weeks prior to recruitment.[11] A DFU was defined as a full-thickness wound below the ankle on a person diagnosed with diabetes.[12] An RCW was defined as a prefabricated knee-high offloading device designed with the intention of relieving mechanical pressure from a specific region of the foot and able to be readily removed and re-applied by a patient.[4] Prior RCW treatment of at least 4 weeks was chosen to minimise potential bias that has been previously reported toward patients having higher adherence in the initial week of prescribing RCW offloading treatment compared with lower stable adherence levels reported for the same patients from week 4 onward until healing following RCW offloading prescription.[11] Exclusion criteria included those unable to ambulate (ie, completely bed or wheelchair-bound) or with a history of cognitive impairment (ie, dementia or Alzheimer's disease).[4 13] All eligible patients meeting inclusion criteria were consecutively invited to participate and were only included after providing voluntary informed written consent. Participant recruitment commenced in October 2019 and concluded in February 2020.

Sample size

Sample size calculations were based on the following assumptions: (i) five factors would likely be included in the final multiple linear regression model based on the only previous similar study identifying five factors associated with adherence in their multiple linear regression model,[6] that a minimum of 10 participants is necessary for each included factor according to statistics texts so as not to overfit such a multiple linear regression model,[14] and 5%–10% of participants may have activity monitor failure or drop out as reported in a previous study of activity in patients with DFU.[15] Thus, assuming five final factors would be included in the final regression model, each factor needing 10 participants, and with a drop-out rate of 10%, we conservatively estimated a sample size of 60 participants was required to address the aims of this study.

Data collected

Multiple sociodemographic, physiological, and psychosocial factors were collected from participants as follows.

Sociodemographic factors

Sociodemographic factors were obtained by participant self-report and included age, gender, living arrangement (living alone, living with family, or primary carer for another household member), highest education level achieved (primary school, secondary school, undergraduate, or postgraduate), employment (employed, unemployed, retired, or self-funded), and family income (the highest income per month in Jordanian Dinar (JD)).[13 16 17]

Physiological factors

Physiological factors were subgrouped into health, limb, and ulcer factors. Most health factors were obtained by participant self-report and included type and duration of diabetes, and history of comorbidities that had been

present for more than >6 months (ie, dyslipidemia, end-stage renal failure, heart failure, hypertension, myocardial infarction, osteoarthritis, or retinopathy).[16] Other health factors were obtained by clinical examination, including body mass index (BMI) and level of activity (measured by Fitbit Flex wrist monitors as outlined later in the outcome of interest). Lastly, the most recent hemoglobin A1c was collected from participants' medical records.

Limb and ulcer factors were obtained by clinical examination of participants by a qualified diabetic foot nurse researcher and included peripheral neuropathy, peripheral artery disease (PAD), foot deformities, previous amputations, and DFU characteristics. Neuropathy was defined if participants were unable to feel a 10 g monofilament on at least two of the three recommended sites (plantar hallux, first, and fifth metatarsal head).[18] PAD was determined using a toe brachial index (TBI) and defined as PAD if the TBI was <0.75 or not PAD if >0.75 TBI.[13 19] Limbs were inspected to detect previous amputations (minor or major) and foot deformities, defined as either having hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, supinated foot type, pronated foot type, or chronic Charcot neuro-osteoarthropathy.[12 17] DFUs were clinically examined for size, depth, and infection characteristics. The size was measured by measuring the product of the length and width of the ulcer area in centimetres square using a tape measure.[13] Depth was graded according to the University of Texas Wound Classification System and defined as: grade 1: no penetration of tendon, capsule, or bone; grade 2: tendon or capsule penetration; or grade 3: joint or bone penetration.[20] Lastly, DFU infection was collected from the most recent diabetic foot clinic record in the participants' medical records.

Psychosocial factors

Psychosocial factors were obtained from participants completing diabetes-related foot psychosocial scales that had all been previously translated into the Arabic language and shown to have high levels of cultural appropriateness and reliability for the Arabic DFU population,[21] including the following scales:

- *Foot care confidence scale (FCCS)*:[22] a 12-item tool using a 5-point Likert scale for each item, which measures patients' confidence to undertake foot self-care activities (eg, washing feet or cutting nails).
- *Footcare outcomes expectations scale (FCOES)*:[23] a 15-item tool using a 5-point Likert scale for each item, which measures patients' expectations regarding the outcomes of performing foot self-care in preventing DFUs (eg, moisturising feet or wearing proper footwear).
- *Patient interpretation of neuropathy scale*:[24] an 11-item tool using a 5-point Likert scale for each item, which measures patients' knowledge on the potential causes of neuropathy and DFUs (eg, self/practitioner-blame, physical causes of DFUs, and duration and time of the onset of DFUs).
- *Neuropathy-specific quality of life scale*:[25] a 16-item tool using a 5-point Likert scale for each item, which measures the frequency of neuropathic symptoms (eg, neuropathic pain, reduced feeling, and motor neuropathy), the related feelings (none to very much bothering), and the related impact on quality of life (not at all to very much) in the last 4 weeks.
- *Offloading-related scale*: an 8-item tool using a visual analogue scale (range 0–10) for each item that measures patients' experience using RCWs, including items for level of comfort,[26–28] level or the ability to perform activities,[27] alteration in sleeping,[27] level of satisfaction,[27 29] perceived heaviness of the RCW,[21] the difficulty of applying the RCW,[21] and the likelihood to use the RCW for any future treatment.[27]
- *Other customised offloading-related scales*: the authors additionally self-designed several items to measure other specific psychosocial aspects related to offloading that had not had a scale designed to capture such aspects to our knowledge, including one 5-point Likert scale item added to the FCCS to measure patients' confidence to adhere to wearing RCWs during all walking steps, one 5-point Likert scale item added to the FCOES to measure patients' beliefs of their healing outcome expectations of adhering to wearing RCWs during all walking steps, and two 5-point Likert scale items to measure patients' available social supports to help apply their RCW (eg, always, usually, sometimes, rarely, or never) and their beliefs that walking a few steps without wearing RCWs is not harmful (eg, totally agree, moderately agree, neither disagree nor agree, disagree, or not agree at all).

Outcome of interest

The outcome of interest for this study was the objective measure of the proportion of participants' adherence to using RCWs during their total weight-bearing activity over a 7-day period (with a minimum to be included of least three full days). This was performed using a validated dual activity monitor method used in previous similar studies[6 30 31] and recently recommended by international experts,[3] and by using reliable Fitbit Flex activity monitors.[32–35] The Fitbit Flex activity monitors have shown good validity and reliability for measuring steps when compared with measuring observed manually counted steps in similar older aged populations as those with DFU.[32–35] One monitor was attached to the posterior aspect of the participant's RCW and fixed in place using adhesive tape to prevent removal so as measure activity when wearing the RCW and the other monitor was incorporated in a wrist band designed to be worn by the participant on their wrist like a wrist watch to measure the total activity of the participant (figure 1).[3 6 30] The wrist monitors have been reported to be worn for longer periods then hip or waist monitors,[36] do not need recharging within a 7-day period,[35] are water proof so they do not need to be removed for any water-based activities, such as showering, like other monitors need to be,[35] and

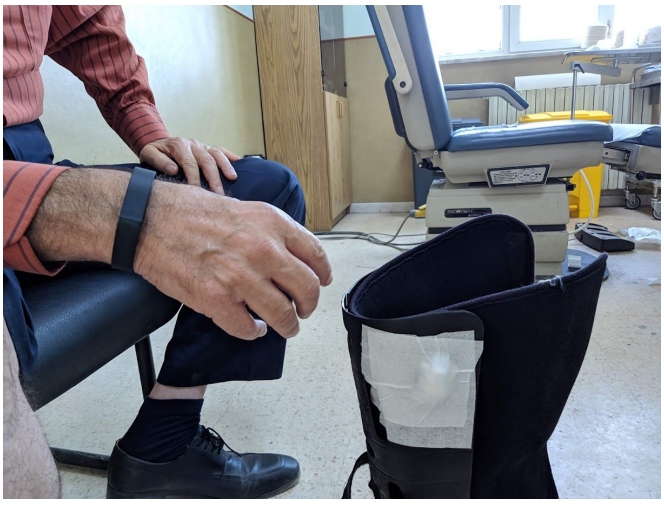

Figure 1 Example of the dual activity monitors attached to the participant's wrist and removable cast walker (National Centre for Diabetes, Endocrinology, and Genetics) (permission was obtained from the rightsholder).

participants were able to choose their preferred color from four options. Participants were instructed to wear the wrist activity monitor continuously at all times for the 7-day period and were provided daily reminders (via phone or text messaging) to continue wearing the wrist activity monitor at all times. Otherwise, participants were informed that the wrist and RCW monitors aimed to simply measure the number of steps for the week people with DFU perform on average, but, the specific purpose of using the activity monitor attached to the RCW to measure adherence was deliberately concealed from participants to avoid biasing their normal adherence behavior.[3] Also, there were no instructions provided by the researchers on wearing the RCW during the study period for the participant or treating clinician so as not to bias usual instructions provided by treating clinicians or the usual adherence behaviors to wearing the RCW of patients.

At the end of the 7-day period, the two activity monitors were returned by participants and all data from the two monitors were time-synchronised, downloaded into a central server and transformed into activity units as per previously validated methods.[6] An activity unit was defined when the participant's wrist activity monitor recorded any step activity during a 15 min period (ie, there were a possible 96 potential activity units in each 24-hour day). Participants were deemed to have been adherent to wearing their RCW during an activity unit if their RCW monitor recorded at least 50% of the steps recorded by the wrist monitor during that same 15 min period as per previous studies.[3 6 30] As per previously validated dual monitor methods, any potential activity unit where either both monitors recorded no step activity or the RCW monitor recorded step activity and the wrist monitor recorded no step activity ('wrist monitor non-adherence'), were excluded to limit any bias for the rare occasions when the participant had not worn their wrist monitor.[6 30 31] The proportion of adherence for each participant was then simply calculated as the proportion of adherent activity units of the total activity units as previously validated.[3 6 30] Daily steps were also reported using the total number of steps per day registered by the wrist monitor.

Statistical analysis

All data were analysed using SPSS V.23.0 for Windows (IBM, Armonk, New York, USA). Descriptive analyses were used to display frequencies (proportions) for categorical variables, mean (SD) for normally distributed continuous variables, and median (IQR) for non-normally distributed continuous variables. Simple linear regression was used to test for unadjusted associations between each variable.

Multiple linear regression was then used to test for adjusted associations. All factors with an unadjusted association of $p \leq 0.1$ were simultaneously entered into the multiple linear regression model and a backward stepwise method was used to eliminate non-significant variables ($p > 0.05$) until only significant adjusted variables remained ($p \leq 0.05$). The model was tested for collinearity (using tolerance (<0.1) or variance inflation factor (>10)). If collinearity was identified, the variables with least statistical significance, or in cases with similar statistical significance, the variable with least clinical causal plausibility was excluded. The model was also tested for residual outliers (Mahalanobis distance and Cook's distance), normality and linearity (normal P-P plot). Missing data were handled by excluding cases with missing data as missing data were minimal.

RESULTS

Overall, 72 patients were eligible for this study, and of those, 61 consented to participate. The 11 patients not consenting included 6 who declined without providing a specific reason and 5 due to an inability to return the activity monitors. Of the 61 consenting participants, 4 had to be excluded due to not obtaining any outcome data, including 2 who had monitors that failed to record any data, 1 who refused to use the monitors after consenting, and 1 who was hospitalized before using the monitors. Thus, 57 participants were included in this study. Only 5.3% was for wrist monitor non-adherence (when the RCW monitor recorded steps and the wrist monitor did not).

Overall, participants adhered to using their RCW for a mean of 33.6% (SD 16.5) of their total weight-bearing activity. Table 1 displays the sociodemographic, physiological, and psychosocial characteristics of the 57 participants. Overall, participants' mean age was 56 years (SD 10), 79% were males, mean BMI was 30.9 (SD 6.3), 95% had type 2 diabetes, 72% had neuropathy, 28% had PAD, 58% had infection and median ulcer size was 1.5cm^2 (IQR 0.5–5.0 cm^2). Participants recorded a median daily number of steps of 2758 (IQR 1729–4726). Table 2 displays

Table 1 Participant characteristics (number (%) or mean±SD unless otherwise stated)*

Characteristics	Total
Numbers	**57**
Sociodemographic factors	
Age (years)	56 (10)
Males	45 (78.9%)
Living with family	53 (93.0%)
Secondary school education	25 (43.9%)
Retired	20 (35.1%)
Family income (JD)*	400 (312–700)
Physiological factors	
Health	
Type 2 diabetes	54 (94.7%)
Duration of diabetes (years)	17.2 (7.3)
HbA1c (%, mmol/L)	8.9 (2.0)
BMI	30.9 (6.3)
Mean steps*	2758 (1729–4726)
Dyslipidemia	28 (49.1%)
End-stage renal failure	3 (5.3%)
Heart failure	7 (12.3%)
Hypertension	32 (56.1%)
Myocardial infarction	6 (10.5%)
Osteoarthritis	7 (12.3%)
Retinopathy	22 (38.6%)
Limb	
Neuropathy	41 (71.9%)
PAD	16 (28.1%)
Foot deformities	41 (71.9%)
Minor amputations	16 (28.1%)
Major amputations	0 (0)
Ulcer	
History of previous ulceration	38 (67.9%)
Duration of ulcer (weeks)*	16 (5–38)
Ulcer size (cm^2)*	1.5 (0.5–5.0)
Deep ulcer (UTWCS grade 2 or 3)	25 (43.9%)
Ulcer infection	29 (58.0%)
Duration of RCW (weeks)*	12 (4–32)
Psychosocial factors	
FCCS	48.9 (10.2)
FCOES	67.3 (10.2)
PIN: self/practitioner blames	14.8 (3.0)
PIN: physical causes of DFU	16 (2.6)
PIN: acute ulcer onset	11.2 (1.9)
NQOL: foot pain	6.2 (3.2)
NQOL: loss of feeling	7.6 (5.2)
NQOL: motor neuropathy	7.2 (4.7)
Level of comfort (VAS)*	5 (5–10)
Ability to perform daily life activities (VAS)*	5 (5–7)
Alteration in activity level (VAS)*	5 (5–8)
Alteration in sleep (VAS)*	5 (0–5)
Level of satisfaction (VAS)*	6 (5–10)
Re-wearing the offloading device in the future (VAS)*	9 (5–10)
Heaviness of the RCW (VAS)*	5 (5–6.5)
Difficulty in applying the RCW (VAS)*	5 (2.5–5.5)
Always having social support when applying the RCW	21 (36.8%)
Totally agree that non-adherence to wearing RCW in few steps is not harmful	15 (23.3%)

*Displayed as median (IQR).
BMI, body mass index; DFU, diabetes-related foot ulcer; FCCS, foot care confidence scale; FCOES, footcare outcomes expectations scale; HbA1c, hemoglobin A1c; JD, Jordanian Dinar; NQOL, neuropathy-specific quality of life; PAD, peripheral arterial disease; PIN, patient interpretation of neuropathy; RCW, removable cast walker; UTWCS, University of Texas wound classification system; VAS, visual analogue scale.

the unadjusted and adjusted associations between variables and the proportion of adherence to using RCWs. Eight factors met eligibility for entering into the multiple regression model including gender, diabetes duration, myocardial infarction, history of previous foot ulceration, PAD, perceived RCW heaviness, level of RCW comfort, and offloading belief that non-adherence to wearing RCW is not harmful (all; p≤0.1). However, myocardial infarction and history of previous foot ulceration were excluded due to collinearity with PAD and duration of diabetes, respectively. After adjustment, the four factors that remained independently associated with adherence in the final regression model included: longer diabetes duration and perceived heavier RCW devices with lower adherence levels; and being female and having PAD with higher adherence levels (all, p≤0.05) (see table 2).

DISCUSSION

We found patients adhered to using their RCW for approximately 34% of their activity or the equivalent of a third of their treatment duration. The factors independently associated with lower adherence levels were being male, having longer diabetes duration, not having PAD, and perceived heavier RCWs. We found no associations with psychosocial-related factors.

To our knowledge, only two previous studies have also objectively measured RCW adherence in patients with DFU with all using a similar dual activity monitor methodology.[6 30] Our finding of 34% adherence in a Jordanian population was similar to the 28% reported in a 2003 US population,[30] but lower than 59% reported in 2016 US and UK populations.[6] A likely explanation is that our study and the 2003 study included only those using knee-high RCWs,[30] while the 2016 study included those using a range of different knee-high and ankle-high offloading devices.[6] Previous studies report removable ankle-high devices have higher adherence than knee-high devices and this may explain some of the difference.[5 37] Furthermore, we recruited patients who had at least 4 weeks

Table 2 Unadjusted and adjusted associations between variables and mean adherence proportion to using RCWs

Variables	Mean (SD) adherence proportion	Unadjusted association		Adjusted association†	
		β	P value	β	P value
Age	–	−0.11	0.43		
Males	31.8 (17.0)	−0.22	0.10*	−0.24	0.02**
Living with family	34.5 (16.4)	0.02	0.89		
Secondary school education	32.1 (15.2)	−0.08	0.56		
Retired	31.2 (13.5)	−0.11	0.42		
Family income (JD)	–	0.08	0.59		
Type 2 diabetes	34.0 (16.6)	0.09	0.51		
Duration of diabetes (years)	–	−0.34	0.01*	−0.44	0.001**
HbA1c (%, mmol/L)	–	−0.03	0.85		
BMI	–	0.05	0.71		
Mean steps	–	−0.04	0.79		
Dyslipidemia	30.8 (16.3)	−0.17	0.21		
End-stage renal failure	39.0 (13.0)	0.08	0.56		
Heart failure	28.9 (15.3)	−0.11	0.43		
Hypertension	30.9 (16.8)	−0.19	0.16		
Myocardial infarction	44.3 (20.4)	0.22	0.09*		
Osteoarthritis	28.5 (18.7)	−0.12	0.38		
Retinopathy	34.5 (15.8)	0.04	0.75		
Neuropathy	33.4 (16.9)	−0.01	0.97		
PAD	39.4 (16.7)	0.22	0.10*	0.30	0.01**
Foot deformities	33.0 (16.1)	−0.06	0.67		
Minor amputations	28.2 (15.3)	−0.21	0.13		
History of previous ulceration	30.4 (15.5)	−0.26	0.06*		
Duration of ulcer (weeks)	–	−0.10	0.48		
Ulcer size (cm^2)	–	0.11	0.41		
Deep ulcer (UTWCS grade 2 or 3)	37.2 (16.5)	0.20	0.14		
Ulcer infection	36.2 (16.5)	0.16	0.22		
Duration of RCW (weeks)	–	−0.12	0.36		
FCCS	–	0.01	0.94		
FCOES	–	−0.19	0.17		
PIN: self/practitioner blames	–	−0.14	0.29		
PIN: physical causes of DFU	–	−0.09	0.53		
PIN: acute ulcer onset	–	0.14	0.29		
NQOL: foot pain	–	0.11	0.42		
NQOL: loss of feeling	–	−0.07	0.60		
NQOL: motor neuropathy	–	−0.02	0.86		
Level of comfort (VAS)	–	0.25	0.07*		
Ability to perform daily life activities (VAS)	–	0.22	0.11		
Alteration in activity level (VAS)	–	−0.13	0.35		
Alteration in sleep (VAS)	–	0.13	0.35		
Level of satisfaction (VAS)	–	0.09	0.50		
Re-wearing the offloading device in the future (VAS)	–	0.17	0.20		
Heaviness of the RCW (VAS)	–	−0.24	0.07*	−0.23	0.05**
Difficulty in applying the RCW (VAS)	–	−0.18	0.18		
Always having social support when applying the RCW	34.0 (16.4)	0.02	0.88		

Continued

Table 2 Continued

Variables	Mean (SD) adherence proportion	Unadjusted association β	Unadjusted association P value	Adjusted association† β	Adjusted association† P value
Totally agree that non-adherence to wearing RCW in few steps is not harmful	40.1 (17.1)	0.24	0.08*		

*P≤0.1 (variables in the bivariate testing were nominated for the multiple regression model); **p≤0.05 (in the multiple regression model).
†Multiple regression model for the study variables, F=6.17, p<0.001, adjusted R^2=0.28.
–, adherence mean is not applicable; BMI, body mass index; DFU, diabetes-related foot ulcer; FCCS, foot care confidence scale; FCOES, footcare outcomes expectations scale; HbA1c, hemoglobin A1c; JD, Jordanian Dinar; NQOL, neuropathy-specific quality of life; PAD, peripheral arterial disease; PIN, patient interpretation of neuropathy; RCW, removable cast walker; UTWCS, University of Texas wound classification system; VAS, visual analogue scale; β, beta-coefficient.

of RCW using experience to avoid any potential bias toward elevated initial adherence levels.[11] However, prior using experience was not reported in the two previous studies and this may have also impacted adherence findings.[6 30] Overall, these findings indicate that patients with DFUs on average adhere to using the removable knee-high offloading treatment for <50% of their prescribed treatment.[6 30] Thus, when considered against the vastly improved healing outcomes consistently found with 100% enforced adherence when using the same knee-high devices made non-removable, this further highlights the critical impact that offloading adherence has on healing outcomes.[4]

We identified four factors to be independently associated with adherence to using RCWs.[6] First, our finding that gender was associated with adherence was not found in the only previous study.[6] A hypothesis may be that males with diabetes are thought to perform fewer foot self-care activities than females, such as adhering to offloading treatments.[38] However, we measured multiple self-care and self-efficacy scales and identified no associations. Thus, our finding may be explained by cultural or ethnic differences between middle eastern and western populations or an artifact of our analysis.[39 40] Regardless, our finding, that males adhere less to DFU treatment than females, may be one reason why males also have been found to have more hospitalizations and amputations,[1] however, this requires further investigation.

Second, we found that longer diabetes duration was associated with lower adherence to wearing RCWs. However, diabetes duration was not identified in the previous study,[6] in reviews of factors associated with adherence to using therapeutic footwear,[41] nor adherence to diabetes medications among people with diabetes.[42] A possible explanation may be that patients with longer diabetes duration need to adhere to many diabetes treatments, and RCW treatment is an additional complex burden that eventually does impact adherence unlike with other less complex treatments. Diabetes duration has also been found to result in more depression,[43] which also may support our explanation of the impact on adherence.[44] Regardless, the impact of diabetes duration on DFU treatment adherence should be explored.

Third, we found that patients with PAD had significantly higher adherence to wearing RCWs. This finding again appears novel, however, the previous similar study excluded patients with PAD and found severe DFU characteristics were associated with higher adherence, such as neuropathic pain and larger ulcers.[6] Furthermore, a similar footwear study found that more severe foot deformities also increased adherence levels to therapeutic footwear.[45] One hypothesis for our finding may be that, similar to other severe DFU characteristics, PAD may indicate to patients that they have more severe DFU pathology, and this may increase adherence levels to treatments if patients perceive they may receive more of a potential health benefit when using the treatment for more severe pathology.[6 45] Conversely, clinicians may need to implement strategies to increase awareness of patients who perceive they have less severe DFU (ie, neuropathic DFUs) to the benefit of adherence to healing. However, another hypothesis may be that our signle non-invasive measure of PAD using a TBI theshold of <0.75, while recommended in guidelines and research standards to be adequate to assess for PAD in people with DFU,[13 19] is not a gold standard invasive measure of PAD,[13 19] and we may have included some false-positive measures for participants without PAD by virtue. Thus, we suggest caution with this finding and we recommend further measures of PAD are used in future similar studies.

Lastly, we found patients who perceived having heavier RCWs had lower adherence. This finding seems to align with previous qualitative investigations that have reported patients consider some RCWs to be heavy.[9 10] A further recent study reported patients also found ankle-high RCWs were lighter and more comfortable compared with knee-high RCWs.[26] This also aligns with quantitative findings showing knee-high RCWs heavier (~1.4 kg) than ankle-high RCWs (~1.0 kg), and conventional footwear (~0.3 kg).[46] However, interestingly our measure was of patients' perception of heaviness, thus patients with what they perceive as a lighter offloading device may have higher adherence.[26] Thus, in future, offloading device manufactures may consider testing perceived heaviness, and clinicians may consider trialing different makes of knee-high RCWs to find those perceived as lighter when first prescribing treatment to try and improve adherence in their patients.[26]

Finally, this study found no significant relationships between adherence and psychosocial factors which were in line with the only previous similar study.[6] This may indicate that psychosocial factors do not influence

adherence to offloading treatment in people with DFUs as much as they do in other conditions. This may also indicate the scales used to measure cognitive beliefs were not specific to offloading adherence and the development of valid offloading beliefs scales may be required in future. Interestingly, previous qualitative studies have reported patients to have an inadequate understanding of the definition of optimal offloading adherence, and thus, education of patients on the importance of wearing the offloading device for all weight-bearing activities may be helpful.[8 9]

This study should be read cognizant of several limitations. First, the design of this study was cross-sectional and was unable to determine causality. Second, adherence was only monitored for 1 week and patients with DFUs may change their behavior when observed for longer periods,[11] and thus, we recommend longitudinal studies in future. However, we did allow for 4 weeks of wearing experience as an inclusion criterion to minimize such potential bias.[11] Third, we cannot exclude the chance of not recording some activity if participants did not wear their wrist activity monitor. However, we reminded patients daily to wear their wrist monitor, the aim of using the RCW monitors was concealed,[6] and any activity unit in which only the RCWs' monitors recorded activity were excluded and this was minimal at only 5.3%. We also would recommend studies investigate adherence during night time and day time to see if adherence is different in different parts of the day and if influenced by different factors. Fourth, the activity monitors used did not measure standing which has been found to influence healing.[11] Last, we did not use psychosocial scales specifically related to offloading adherence.

CONCLUSIONS

In conclusion, adherence to using removable knee-high offloading treatment was found to be low among patients with DFUs. This finding further highlights that clinicians should recommend non-removable knee-high offloading devices as the gold standard offloading treatment for people with DFU to ensure optimal plantar pressure reduction and importantly treatment adherence. However, when non-removable knee-high offloading devices are contraindicated or not tolerated by the patient, clinicians should recommend removable knee-high offloading devices as the second line of treatment and when doing so should consider optimising adherence levels, including by addressing the factors found in this study to be associated with lower adherence levels if possible, such as being male, longer diabetes duration, not having PAD, and perceived heavier RCWs. Regardless, further research is needed to continue to build on these findings in this important area of offloading treatment adherence in people with DFU.

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