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Off-Loading Devices for People with Diabetic Neuropathic Foot Ulcers: A Rapid Qualitative Review

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Abbreviations

USD	United States Dollar

Context and Policy Issues

Diabetes is a serious chronic disease; it is among the top 10 causes of death in adults globally [1]. Recent research estimated that 9.3% of world's population or 463 million people were living with diabetes in 2019, and the number is expected to increase to 10.9% of world's population or 700 million people by 2045 [2]. An estimated expenditure of 727 billion USD every year [1] is dedicated to diabetes globally.

Diabetes is also a serious issue in Canada. In 2015, 9.3% of the population was estimated to be living with diabetes, and the number is expected to rise to 12.1% by 2025 [3]. In 2015, Canada spent 17 billion USD on diabetes-related expenditures, the seventh highest spending worldwide [1].

Diabetes is the leading cause of renal disease, blindness, and amputation in adults [4]. Diabetes may cause diabetic neuropathy characterized as weakness in muscles and loss of sensation in the extremities. Loss of sensation combined with continuous pressure from walking, trauma, or foot deformities can increase the risk of developing a diabetic foot ulcer[5].

Between 4% and 10% of diabetic patients develop foot ulcers [6 7]. Diabetic foot ulcers can lead to infection and amputation if untreated [8]. In Canada, people with diabetes are 12 times more likely to be hospitalized due to non-traumatic amputation of lower limbs [3]. Amputation has important social, emotional, and psychological consequences for patients. As such, it is essential to treat or prevent diabetic foot ulcers.

Diabetic offloading devices are used to treat or prevent foot ulcers. Their purpose is to redistribute pressure on plantar surfaces thereby reducing the risk of foot ulcers and infection [9]. Common offloading modalities include removable cast walkers and total contact casting. For example, total contact casting uses fibreglass or plaster to support lower legs by redistributing pressure from ulcer to the entire foot [10]. Redistributing pressure helps to manage swelling and reduces the risk of foot infections [11 12].

Total contact casting and removable cast walkers appear to be clinically effective. One systematic review of randomized controlled trials found that healing rates for patients who were treated by total contact casting was between 74% and 95%, and for removable cast walkers was 52% and 85% [13]. However, there are issues pertaining to adherence to offloading, which may explain the difference between the effectiveness of total contact casting and removable cast walkers [10]. One systematic review found that non-removable offloading devices – such as total contact casting – confers better outcomes for diabetic foot ulcers treatment than removable devices by limiting patients' ability to remove the device thereby increase adherence [14].

Given the important role offloading devices can play in treating or preventing diabetic foot ulcers, there is a need to clarify the challenges patients with diabetes face adhering to different devices. This rapid qualitative evidence synthesis analyzes the perspectives, experiences, and preferences of patients with diabetes and of podiatrists using offloading devices for the treatment of diabetic foot ulcers.

Research Questions

1. How do people living with type 1 or type 2 diabetes understand the use of offloading devices for the prevention and treatment of diabetic neuropathic foot ulcers? What are their experiences with these devices and how do they describe their expectations?
2. How do people caring for (e.g., professional health care providers or family and friends) those living with type 1 or type 2 diabetes understand the use of offloading devices for the prevention and treatment of diabetic neuropathic foot ulcers?

Key Findings

This rapid qualitative review analyzed 12 studies describing podiatrists' and patients' experiences using offloading devices. This review identified several challenges that patients face adhering to various offloading modalities. The most common challenges were mobility and autonomy, patients' perceptions of the device effectiveness, and how offloading devices affected patients' self-image and social interactions. First, patients cited how some offloading devices were heavy and difficult to use, which decreased their willingness to use them consistently in their daily lives. Patients also preferred not to use offloading devices in their homes because they were not designed for comfortable movement around the house. Second, patients who believed that the device provided quick ulcer healing were more likely to use offloading devices in the long-term. However, when patients' expectations for healing were not met, their adherence to offloading decreased. Some patients were also concerned about how some devices may increase the risk of falls or cause new ulcers, particularly with devices that did not fully immobilize affected areas. Third, patients' adherence depended on how their new self-image with the offloading device fit with family and community norms. Some patients viewed the device as a symbol of a disability that affected their social status in their communities, especially when strangers reacted negatively to the device in public. Patients needed time to reflect on how they would use the offloading device in their daily lives; adequate time enabled patients to accept a new self-image that incorporated offloading device use, thereby increasing adherence in the long-term. Patients also expressed challenges with purchasing offloading devices, particularly older patients who were on a fixed income and had to negotiate between broader self-management costs. Maintaining, repairing, and replacing offloading devices was also costly for these patients. Finally, this review found two studies examining podiatrists' perspectives, which generally mirrored patients' experiences and challenges using offloading devices. Podiatrists adopted two approaches to recommending offloading: an aggressive modality that was changed to a less aggressive version because of adverse outcomes, or a moderate modality that was changed to a more aggressive version because of slow healing.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including Ovid MEDLINE and SCOPUS. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were offloading devices and diabetes and foot ulcers. Search filters were applied to limit retrieval to qualitative studies. The search was also limited to English language documents published between January 1, 2010 and May 5, 2020.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Inclusion Criteria

Setting	Community or institutions (e.g., hospital, long-term care home, retirement home etc.)
Population/Perspective	Q1: People living with type 1 or type 2 diabetes who are considered at risk of, or have already developed, diabetic neuropathic foot ulcers (ulceration below the ankle) Q2: People caring for (professionally, or as friends/family) those living with type 1 or type 2 diabetes who are considered at risk of, or have already developed, diabetic neuropathic foot ulcers (ulceration below the ankle)
Intervention	Q1-2: Offloading devices (also known as pressure relieving devices) for foot ulcers including but not exclusive to total contact casting, removable cast walkers, and irremovable cast walkers, footwear (e.g., Darco shoes), foot insoles, and knee scooters; surgical methods for offloading
Comparison	Not applicable
Evaluation	Q1-2: People's (and their care providers') understandings of, expectations for, and experiences with offloading devices for diabetic foot ulcers (inclusive of how these devices are accessed); people's (and their care providers) experiences living with, or living at risk of developing, neuropathic foot ulcers (e.g., impact of ulcer on daily activity, coping with pain or walking disability

Exclusion Criteria

Articles were excluded if they did not meet the inclusion criteria outlined in Table 1, they were duplicate publications, or were published prior to 2010. Studies on the following populations were excluded from this review: patients with ischemic ulcers, patients with ulcers from rheumatoid arthritis, and patients with leprosy who use pressure-relieving devices to manage their health. This review also excluded studies on general self-management challenges that patients with diabetes face. For studies that included a section on offloading devices or footwear, this review analyzed just those sections.

Critical Appraisal of Individual Studies

The included studies were critically appraised by one reviewer using the Quality of Reporting (QuaRT) tool as a guide [15]. This tool assesses the reporting quality of included studies based on four commonly mentioned methodological characteristics: question and study design, selection of participants, methods of data collection, and methods of data analysis. Summary scores were not calculated to describe study quality; rather, the strengths and limitations of each included study were narratively and summarized in Appendix 4. Results of the critical appraisal were not used to exclude studies from this review.

Data Analysis

Descriptive Analysis

One reviewer extracted basic details on study design, methods, and participant characteristics using a data extraction form. The following study details were recorded: research objectives, country of publication, study design and qualitative methodology or analytic approach, data collection method, inclusion criteria of participants, sample size, proportion of male respondents, age range, and type of device if reported. One reviewer performed summary statistics of these characteristics and summarized them in Appendix 2.

Analytic Approach

Data analysis was informed by the qualitative meta-synthesis approach [16]. This evidence synthesis methodology aggregates the findings across included studies while maintaining the original meaning of each study in the final integrative interpretation. Using the constant comparative method and constructivist grounded theory [17], one reviewer retrieved, compared, and synthesized findings to develop an overall interpretation of the themes and concepts captured in included studies. The reviewer emphasized developing an interpretation that maintains coherence with the relevant policy decisions.

One reviewer conducted two cycles of coding. In the initial coding phase, the reviewer analyzed three studies from different countries and types of device. These three studies were specific to the challenges patients with diabetes face in using offloading devices. The reviewer worked through the results, discussion, and conclusion sections of these studies to understand, problematize, breakdown, and reform themes and concepts through a line-by-line analysis. The reviewer moved quickly through the data to acquire a broad understanding of relevant themes and concepts to develop a coding schema that summarized the saliency of various issues patients facing using offloading device. At this point, the reviewer determined whether useful subgroup analyses could be conducted such as providers' and patients' perspectives, and different experiences across distinct offloading devices. The reviewer then used the coding schema to extract relevant themes and concepts from the remaining studies. Findings from these studies either substantiated existing themes and concepts in the schema or added new ones. The focus at this stage was to retrieve themes and concepts that may be useful for policy discussions as well as those that might provide a new perspective on the research topic.

In the second focused coding phase, the reviewer revisited and reorganized all coding to achieve theoretical saturation between and within each theme by identifying where there was consistency, redundancy, and divergence between themes. The reviewer then developed a narrative summary for each theme and collated all summaries to develop an integrative and holistic interpretation of findings.

Summary of Included Literature

Quantity of Research Available

A total of 107 citations were identified in the literature search. Following screening of titles and abstracts, 84 citations were excluded and 23 potentially relevant reports from the electronic search were retrieved for full-text review. Two potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 13 publications were excluded for various reasons, and 12 publications

met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA[18] flowchart of the study selection.

Summary of Study Characteristics

Study Design or Analytic Approach and Data Collection Method

Of 12 included studies, eight (66.7%) were qualitative only [19-20], and four (33.3%) were mixed- or multiple-methods [21 22 23 24].

For the qualitative studies, and the qualitative portion of mixed- or multiple-methods studies, three (25.0%) used phenomenology [19 25 26], three (25.0%) used framework analysis [27 28 20], and one study used each of the following: content analysis [24], grounded theory [29], qualitative description [30], and thematic analysis [22]. Two (16.7%) studies did not report their qualitative methodology [21 23].

Eight (66.7%) studies used semi-structured interviews as their only data collection method [19 29 30 27 28 25 26 20]. Two (16.7%) studies used focus groups only [22 23], one (8.3%) used a semi-structured survey [24], and one (8.3%) used qualitative patient comments from an electronic health record system [21].

Country of Origin

Four (33.3%) studies were conducted in Australia [22 23 24 20], and three (25.0%) were conducted in the United Kingdom [27 28 25]. Two (16.7%) studies were conducted in Canada[21 29], and one study was conducted in each of the following countries: Malta [19], Singapore [26], and Sweden [30].

Patient Population

In total, 10 (83.3%) studies included patient populations, and two (16.7%) included healthcare provider populations [23 24]. Overall, the perspectives and experiences of 193 patients with diabetes were captured in patient-only studies. All studies except one included adult patients with diabetes [30]. The perspectives of 59 podiatrists were captured in the two provider-only studies.

Eight (66.7%) studies reported the proportion of male participants [19 30 27 23 28 25 26 20], whereas four (33.3%) did not report this information [21 29 22 24]. The proportion of male participants in included studies ranged from 41.1% [27] to 90.9% [20]. Five out of the eight studies that reported the proportion included more than half male participants in their study.

Seven (58.3%) studies reported information on participants' median age or age range [21 30 27 23 28 25 20], whereas five (41.7%) did not report this information [19 29 22 24 26]. The age of participants ranged from seven [30] to 97 [27] years.

Devices

Eight (66.7%) studies identified the offloading device of interest; four (28.6%) were interested in shoe insoles or padded heels [21 22 28 25], two (14.3%) in total contact casting or instant total contact casting [29 23], one in removable and irremovable cast walkers [29], and one on multiple unspecified non-removable offloading devices [24].

Summary of Critical Appraisal

A summary of strengths and limitations of each included study can be found in Appendix 4.

All studies except one [20] provided a clear research question or objectives that guided the study. Similarly, 10 (83.3%) studies identified a qualitative study design or analytic approach [19 30 29 22 27 28 25 24 26 20]. Of these 10 studies, six provided a justification for their choice of study design in relation to the research topic and objectives [29 22 27 28 25 26].

More studies provided an adequate description on selection and recruitment of participants, data collection methods, and data analysis processes, than studies that did not provide an adequate description of these methodological characteristics. For selection and recruitment, four (33.3%) studies provided little or no description [19 30 24 20]; three (25.0%) lacked sufficient detail on data collection methods [21 19 23]; and six (50.0%) lacked sufficient detail on data analysis [21 19 22 23 28 24]. Of note, 10 (83.3%) studies did not discuss study rigor or quality [21 19 29 30 22 23 28 24 26 20].

In conclusion, while almost all studies identified clear research questions and a study approach, fewer studies provided sufficient descriptions of other methodological characteristics, most notably data analysis. This observation has important implications for interpreting the findings of this qualitative review that reflects publishing patterns of primary qualitative health research. Qualitative researchers often compromise between the quality and comprehensiveness of their findings against providing an adequate description of methodological details in the submitted manuscript, because of journal word count limitations and other factors. As a result, reviewers may intentionally limit their discussion on methodology and methods – to provide more space to illustrate the qualitative findings comprehensively – giving an impression that the study is lacking sufficient methodological detail. Therefore, it is important to consider that lacking sufficient methodological detail in the main manuscript may not be an accurate indicator of study quality.

Results

Using an offloading device is a complex collection of interpretations and reflections regarding the effectiveness of footwear and how it fits with patients' everyday activities. In part, this complexity involves evaluating the needs of each situation or activity when deciding whether to wear an offloading device, as well as reflecting on the perceived immediate risk and sense of well-being that the device confers [25 26]. Patients in multiple studies reported a variety of challenges with wearing offloading devices in the comfort of their homes. While these patients reported using offloading devices to reduce their ulceration risk, consistent behavior change and adherence to devices was more challenging to maintain [25].

Long-term adherence to offloading devices was highly dependent on "personal regulating values" [25]. These values are individually constructed and include self-image, everyday function, environment and activity risk, and pivotal events that increased their perceived susceptibility of ulceration [25]. Patients are more willing to accept offloading devices that offer greater function and participation in everyday life, contributing to stronger adherence [26]. Personal acceptance also depends on whether the offloading device is aligned with patients' self-image and visual appearance preferences. However, patients require time to incorporate offloading devices into their self-image, which involves rationalizing its functional benefit and changing lifestyle as a result [19 26]. The following sections elaborate

on this complex interplay between adherence to using offloading devices, their fit with everyday activities, and self-image.

Barriers to Offloading Device Adherence

Mobility and Autonomy

The relationship between using offloading devices and patients' mobility and autonomy was the most commonly discussed topic in included studies. This topic comprised how offloading devices disrupted everyday activities, how they improved mobility, and using devices indoors.

Patients in eight studies described how using offloading devices disrupted their life routines [19 29 30 22 28 25 26 20]. Patients in one study believed that using offloading devices was an additional burden on their diabetes-related self-management [22]. Ulceration and using offloading devices has important impacts on patients' daily mood and routines:

> I do not have the same inclination as before...now I want to be at home and watch TV. Before...during the weekends we visited my friends but now I have no desire for it...our sexual life has been affected...I don't have any desire [30].

This disruption to everyday activities caused by offloading devices was salient for patients who perceived the device to be heavy and bulky, restricting their ability to perform activities of daily living such as showering [19 29 28 20]. As a result, patients were required to modify their everyday lives dramatically to incorporate the continued use of offloading devices: changing travel plans to heal the ulcer, changing exercise habits to prevent new ulcers, reducing movement in the house, and reducing movement when fatigued or climbing stairs [30 28 20]. Patients also expressed concerns about exposing their offloading device – specifically therapeutic footwear and orthotics – during rainy seasons, which restricted their willingness to participate in daily activities [26]. While patients on total contact casting believed that not being able to remove the device while sleeping or showering caused major disruption to their daily lives, patients on removable cast walkers found it heavy and bulky that restricted their daily movement [29]. Patients also reported challenges in ensuring that wound dressings fully covered the ulcer [30].

Conversely, patients in seven studies noted that offloading devices improved their mobility and autonomy in everyday activities [21 19 29 27 28 25 20]. Patients in one study expressed dramatic improvement in their ability to move with foot ulcers, and as a result experienced an increased sense of freedom [25]. The desire to use offloading devices to heal ulcers was stronger in patients who perceived that devices helped them to participate more meaningfully in hobbies, work, and family activities [20]. In general, patients believed that cast walkers promoted ulcer healing while allowing for some mobility that they appreciated [29]. Patients using padded heel dressing found that it reduced pain and allowed them to resume physical exercise and social activities that were originally limited because of ulceration [21].

Patients in six studies identified reasons for not using offloading devices in their homes, while acknowledging the recommendation to do so by their health care providers [19 27 28 25 26 20]. For some patients, using offloading devices in their homes was too intrusive:

> Well I don't really need to, if I want to go to the toilet I don't really need to put me shoes on to go up the stairs do I ya know, also if I'm a like gonna go up and have a shower [25]

Other patients expressed a preference to "relax" when home which required removing bulky offloading devices that they wore throughout the day [25]. Patients believed that offloading

devices that aid ulcer healing were not designed for house use [27]. For this reason, some patients wore slippers or socks inside their homes, while consistently using offloading devices outdoors [28]. Conversely, patients in one study from Singapore noted that they did not wear their offloading device in their homes because of cultural and family norms [26].

Device Mechanics

Patients identified challenges with applying and maintaining offloading devices and navigating device mechanics. In general, patients preferred removable offloading devices because it enabled them to continue their everyday lives:

> The air cast I wore for quite some time, and I was so thankful to be able to take it off at night and, if I had an itch in my leg to be able to put some cream on it or something or give it a little scratch or whatever. So it is, in terms of mobility and living your life, a lot better [29]

Removable cast walkers also were easier to apply and remove that did not require regular appointments with healthcare professionals [29]. However, patients expressed anxiety when padded heel dressing, wound dressings, and total contact casting visibly hid the ulcer from their view [21 30 29]. Patients in one study imagined their ulcer worsening when the device hid it from their view; their anxiety was exacerbated when patients experienced challenges keeping dressing in the right location or checking wound dressing [29 20]. For removable cast walkers like air casts, patients expressed challenges interacting with certain device mechanics such as air bags and straps; for example, patients who suffered from neuropathy expressed difficulty in inflating air bags in removable cast walkers:

> It was relatively easy, when you do fill in the air bags. Trying to make sure that your foot doesn't move around too much—that was a trickier part about how much pressure to put in. And it would never stay constant. You'd always have to adjust it throughout the day [29]

Perceptions of the Device's Effectiveness

Patients in eight studies reported expectations from using offloading devices [19 30 29 22 25,28 26 20]. Patients sought to "stay well" and avoid extreme complications of foot ulcers such as amputation, which they believed offloading devices would prevent [20]. Patient perceptions of device effectiveness were so important that one study found it to be the core factor in improving adherence to offloading device use [19]. Patients across multiple studies believed that offloading devices were integral to successfully treating their ulcers, as well as preventing future foot-related complications [19 29 22 25 26]. However, some patients preferred to build confidence in the offloading device first before using them consistently in their daily lives [28].

Not all patients expressed positive expectations; some expressed uncertainty in the device's effectiveness or the belief that it increased the risk of unintended health outcomes such as falls or even new ulcers. Patients in one study believed that foot ulcers could not be prevented at all [30]. Similarly, patients in other studies believed that cast walkers were ineffective because they did not fully immobilize their feet, allowing for minor movements that exacerbated the ulcer and increased the risk of new ulcers [29]. Patients in one study also expressed uncertainty in whether therapeutic footwear and orthotics provided adequate protection against ulcers, which decreased long-term adherence to the device [26].

Patients were concerned about the prolonged healing time required by certain offloading devices, in particular, removable cast walkers and therapeutic footwear [29 26]. The prolonged

healing time was perceived by some patients as a lack of progress that affected their confidence and continued, consistent use of offloading devices [29 20]. This was especially problematic for patients who modified their everyday life dramatically to incorporate the offloading device. Patients in one study expressed how they accepted the various "inconveniences" of offloading devices (i.e., heavy, bulky, lack visual appeal, etc.) for the purpose of healing their ulcer. When their expectations were not met, their adherence to devices decreased [29].

Expectations of healing were overshadowed by concerns about unintended health outcomes from using offloading devices that included an increased risk of falls or new ulcers [21 29 28 26 20]. Patients stopped using the device as a precaution to avoid falls, even while acknowledging that the devices were not the primary cause [28]. Patients believed that the design of offloading devices – bulky and hard to use – may increase fall risk for older patients [28]. Patients who experienced a fall had to decide between their perceived risk of falls with the increased risk of ulceration if they chose to forego offloading devices [26]. Patients in two studies also believed that continued use of cast walkers changed their walking, gait biomechanics, and increased hip problems and other injuries [29].

> I had to buy an offloading boot, which wasn't very easy to walk with. It altered my stance, and I ended up getting hip problems. And it was bulky, and it wasn't very easy to get around at all [29]

Self-image and Restoring Social Normalcy

Patients' self-image depended on beliefs about how devices provide "normal" function in everyday activities. "Normal" function was often at odds with the desire to fit in with the social norms of family, friends, and the community. Patients in two studies noted that using offloading devices emphasized to them (and others) that they were not living a "normal" lifestyle because of the medical condition that affected them [25 26]. Offloading devices were viewed as a symbol of disability, which affected patient well-being and adherence. Offloading devices must be accepted within cultural and social norms to increase patient adherence, which requires that offloading devices achieve social normalcy [25]. Restoring normalcy was encouraged or discouraged by the reactions of their family, friends, and strangers [19 26]. For example, certain patients described how strangers in public reacted negatively when seeing offloading devices; conversely, other patients found their family and friends reacted positively because they understood the value of device [19 26].

> I just ignore it and you know people understand. Most of the people who meet me and see me, they understand my condition you see. So I feel eh nothing wrong with the shoe what. It's nothing [26].

Restoring normalcy also depended on patients' perceived visual appeal of offloading devices [19 27 25]. In two studies, patients did not want devices that "look orthopedic" or were "ugly" [19 27]. Patients continuously evaluated themselves and what they wore with the offloading devices they used; as a result, patients expressed desire for shoes that aligned with their fashion preferences [27 25].

Patients needed time to develop a new self-image that incorporated daily use of offloading devices, particularly when the device did not fit with their fashion preferences [26]. As patients accepted and used the offloading device in their daily lives, they negotiated between values and preferences. In two studies, patients expressed negotiating between their perceptions of social normalcy against the need to heal their ulcer rapidly [27 25]. While this negotiation was difficult for some – one patient described how they hid their offloading device when

looking in the mirror – the importance of healing quickly eventually outweighed any concerns with self-image and self-presentation [25]. For patients who were unable to negotiate between these values, patients withdrew socially for the duration of ulcer healing [27].

Device Cost

Patients in seven studies identified the costs to purchasing offloading devices as a barrier to consistent and long-term use [21 19 30 29 22 27 20]. In general, patients found that purchasing an offloading device depended on their income, which was fixed for patients and had to be negotiated between activities of daily living and other diabetes-related self-management costs [29 27]. For patients with fixed incomes, the cost of offloading devices primarily determined which one they purchased, irrespective of their preferences for healing and recovery. For example, patients in one study reported how they used removable cast walkers instead of total contact casting because the latter was more expensive since it required multiple visits to the clinic and more materials [29]. Importantly, patients chose the cheaper alternative while acknowledging that total contact casting may provide superior benefits to healing [29].

> So because I can't afford to do that−even with insurance it's not very affordable− we're trying the air cast, and this past 2 weeks, it hasn't really been helping with the ulcer at all. If anything, it's made it worse [29].

Patients also expressed challenges with purchasing different offloading devices recommended by their healthcare provider when the devices they had previously purchased were not showing a positive impact on healing [29]. At the same time, patients were concerned about the costs associated with repair and replacement of offloading devices [19 29 22 20]. This concern was more prevalent for therapeutic footwear and orthotics because patients believed that they required regular replacement since they deteriorated quicker than cast walkers.

> My main concern...how long does this (insole) last? How long do you have to replace it? On the cost side of things, that would be a big factor for me 'cause one, I'm broke and two I can't justify spending money on stuff that I feel I wouldn't need personally [22].

Lack of Information

Patients in six studies reported lacking essential information for using offloading devices accurately and consistently [30 29 22 25 26 20]. Patients preferred more information on the following: device function, inflating air bags in removable cast walkers, general advice on foot care, relationship between ulceration and offloading devices, using footwear in wet weather, and other self-care practices to accompany offloading device use [30 29 22 25 26 20].

Podiatrist Perspectives and Experiences

Podiatrist concerns and experiences with offloading devices mirrored patients' perspectives and challenges. In general, health care providers reported that offloading devices may be costly, bulky, and heavy that might reduce adherence [24]. Podiatrists also mentioned lifestyle, physical, psychological, and religious or cultural barriers to adherence [24]. Podiatrists agreed that offloading devices that do not show signs of improvement reduce adherence [24].

Podiatrists described different approaches to recommending offloading devices. Some podiatrists selected the most aggressive offloading device at first such as total contact

casting that only changed when they believed that the device disrupted healthy circulation [27]. This group of podiatrists generally favored healing over patient preferences for convenience and retaining mobility and autonomy in daily lives. Conversely, another group of podiatrists selected a moderate offloading device initially and escalated to an aggressive modality when there was no improvement [24]. Overall, podiatrists who had better access to offloading devices showed high work satisfaction [23]. Podiatrists also described barriers to providing complete services to patients because of an inadequate number of trained podiatrists, inflexibility in tailoring offloading devices to patient preferences, lack of on-call staff for patient emergencies, and podiatrist knowledge and skill [23 24].

Recommendations for Improving Offloading Device Adherence

Patients in six studies mentioned the desire to have greater freedom and participation in decisions relating to their care and offloading device use [30 22 28 25 26 20]. One study identified the need to transform the professional-centric approach to a more collaborative relationship with patients [26]. This required having a collaborative discussion about how patients might use the offloading device in their daily lives, connecting the device to patients' sense of well-being and function, focusing on patients' social and familial goals in relation to treatments, and integrating offloading device use as a routine similar to brushing teeth [25 20]. A collaborative relationship may aid in recognizing and incorporating patient preferences in device-related decisions that may also increase sustained adherence. A collaborative relationship may also facilitate acceptance of offloading devices in patients' everyday lives and routines. Another approach to achieving greater participation is by having other expert patients share their experiences with foot ulceration and their approach to using offloading devices in their daily lives [25].

An important part of strengthening a collaborative relationship is by having a conversation about devices that is individualized to each patients' preferences. This requires allowing more flexibility and choice in the design and visual appeal of offloading devices. Patients preferred shoes that were quick to wear, comfortable and soft, lightweight, appropriate size, with adequate ventilation, and improved ability to see the ulcer [19 30 28 20]. Some patients identified specific design recommendations: lightweight with Velcro fastening, molded foot bed, cleated rubber outsole, close fitting, tight laces, increased tread, rigid sole, soft shoe insole, and waterproof [28 25 26].

Limitations

While the issues summarized in this review offer important insight into the challenges that patients face using offloading devices, the body of evidence is somewhat limited due to the quality and scope of included studies.

First, this review was limited to patients with diabetes using offloading devices for foot ulcers. This review excluded studies on other patient populations who also use similar offloading devices for foot ulcers, such as patients with leprosy and rheumatoid arthritis. While not in the scope of this review, the views and experiences of these other populations can offer an important comparative lens to clarify and identify why specific challenges exist for certain populations depending on factors associated with their unique chronic disease and self-management activities. Not all challenges from other patient populations may be applicable for patients with diabetes. However, the comparison with other similar populations may delineate which aspects of various chronic medical conditions confer which daily challenges that make adherence to offloading problematic.

Second, this review found only two studies with health care providers' experiences and perspectives. While this review found that health care provider experiences were parallel to patient experiences, the conclusions are limited because of the low number of studies. Similarly, the perspectives of other health care providers involved in foot ulcer healing are also missing such as family physicians and orthotists.

Finally, this review found self-image and self-presentation to be essential determinants of device adherence. However, these factors highly depend on individual and community culture that are difficult to apply to the Canadian context, especially when only two included studies were conducted in Canada and one study discussed these issues. More primary research is needed on how self-image and self-presentation affect adherence to offloading devices in Canadian communities.

Conclusions and Implications for Decision or Policy Making

This rapid review found 12 studies on patients' and providers' experiences using offloading devices for diabetic foot ulcers. This review described challenges patients face using offloading devices consistently in their daily lives.

Mobility and Autonomy: patients described how using offloading devices disrupted everyday activities and life routines. The heavy and bulky nature of offloading devices limited their physical ability to move and perform activities of daily living such as showering. Patients were required to modify their lives dramatically to incorporate the offloading device. Conversely, some patients believed that offloading devices increased their mobility and movement that was restricted by the ulcer. However, patients generally did not wear offloading devices in their homes, either because they caused major inconvenience moving around the house, or due to cultural and family norms.

Device Mechanics: patients expressed challenges with applying and maintaining offloading devices and navigating device mechanics. Some offloading devices visibly hid the ulcer, which caused anxiety for some patients as they were unable to determine whether the ulcer was healing. Patients who experienced mobility challenges found it difficult to interact with certain device mechanics such as inflating air bags and using straps for removable cast walkers.

Perceptions of the Device's Effectiveness: patients expressed two contrasting expectations from their offloading device: an expectation in its ability to heal and prevent ulceration, and uncertainty in device effectiveness and concerns of unintended health outcomes such as an increased risk of falls and development of new ulcers. Patients also expected that offloading devices would heal their ulcers quickly; when these expectations were not met, adherence to device use decreased.

Self-image and Restoring Social Normalcy: patients' self-image depended on beliefs regarding how devices provide "normal" function in everyday activities. Patients' perceptions of themselves was swayed by the reactions of family, friends, and strangers, and broader community norms. Patients who viewed the device as a symbol of disability expressed a more challenging time to adhering to offloading. Family and friends who understood the value of the device alleviated such concerns, thereby improving adherence to using the device. Patients also negotiated between the desire for social normalcy and ulcer healing; however, ulcer healing was eventually prioritized over other concerns for most patients in included studies.

Device Cost: patients with fixed incomes struggled to purchase an offloading device that provided superior healing. Patients' decision to choose a cheaper alternative was primarily directed by their purchasing power and insurance coverage, irrespective of their preferences. Costs associated with the device included materials and clinic visits, as well as transportation and traveling costs. Patients also expressed concern with the costs associated with changing offloading devices to achieve better outcomes, and costs with device repair.

Lack of Information, patients expressed a need for more information on device function and use in different circumstances, as well as guidance on other self-care activities that they can implement to promote ulcer healing alongside offloading.

Podiatrists' Perspectives and Experiences: podiatrists' perspectives mirrored patients' experiences and challenges with device use. Podiatrists mentioned physical, lifestyle, psychological, and religious or cultural barriers to adherence. There were two approaches to recommending offloading devices to patients: podiatrists who selected aggressive modalities that changed when there were adverse outcomes, or podiatrists who selected moderate modalities that escalated when there were signs of slow improvement.

Finally, *Recommendations for Improving Offloading Device Adherence*: patients expressed a desire for greater freedom and participation in decisions relating to their care and offloading device use. Included studies provided suggestions for improving participation such as collaborative discussions between health care providers and patients, focusing on how patients would use the offloading device in their daily lives, and providing an opportunity to speak with other patients. Patients also expressed specific suggestions to improve the design of offloading devices that would make them easier to use such as making it lightweight and waterproof.

Implications for Policy Decisions

Prevention vs. Treatment

Patient motivations for using offloading devices for prevention versus treatment of ulcers differed across studies and countries. Overall, it was challenging to determine whether or how patients differentiated between the preventive and curative goals of offloading devices; most studies discussed the use of offloading devices in the context of treatment. Two studies included sections that discussed patients' motivation to use offloading devices to prevent new ulcers [29] [22]. Patients who were oriented towards the preventive use of offloading devices were in the process of ulcer healing; preventive goals were more salient for patients who had prior experience with ulceration. Prevention was also mentioned in one study in the context of complications of untreated foot ulcers such as amputation [29]. Conversely, in one study, patients were unaware of the preventive purpose of offloading devices [30]. There is some evidence indicating that treatment and prevention go together; whereas patients were focused on treating their existing ulcer when using offloading devices, they took certain actions to prevent future ulcers or severe complications such as amputation. It may be the case that the preventive use of offloading devices is a lower priority at the start of ulcer healing as patients adjust to the device in their daily lives; but prevention becomes the primary motivator to continue using offloading device once the ulcer has healed. Patients who faced extreme mobility challenges because of ulceration may be keener to continue using offloading devices after their ulcer has healed to prevent future ulcers.

Cost of Offloading Devices

The cost of offloading devices was an important determinant for patients in device decision-making and everyday use. Some devices cost more than others. For example, total contact casting may require more clinic visits than cast walkers. For patients who do not have access to regular transportation, these additional visits may become a financial burden that they consider when deciding which device to purchase. While patients may express preferences for certain devices – preferences that may increase adherence to continued use – these preferences are not the main decision-making factor if patients' purchasing power or insurance coverage did not allow for greater freedom in device choice. This is especially problematic for older patients with diabetes who have fixed incomes and numerous other therapies to manage that are also costly. These reflections indicate that reducing costs that also allow greater flexibility and freedom in device choice may increase adherence and healing rates, without the need to sacrifice one for the other. These reflections also emphasize the need for insurance coverage to allow for flexibility in different offloading devices.

Podiatrists' Approaches to Offloading Recommendations

This review found two groups of podiatrists: those who recommended aggressive modalities and decreased due to adverse outcomes, and those who recommended moderate modalities that intensified because of slow progress. There are two important considerations with regards to podiatrists' approach to recommending offloading devices. First, as this review has shown, there are differences in patients' preferences towards offloading devices. While some patients privilege convenience and may choose an offloading device that allows greater range of daily movement, others may accept reducing their daily movement temporarily for faster healing. Podiatrists may consider adopting a variety of approaches to recommending offloading devices depending on patient preferences, experiences, and other factors associated with their medical condition. For example, while some patients believed that certain offloading devices were ineffective because they did not completely immobilize the affected areas, aggravating the ulcer and causing new ulcers, other patients expressed an explicit preference for devices that were looser and allowed greater circulation. This discrepancy is one of many that exemplifies how the approach to device recommendations must involve a collaborative discussion between patients and healthcare providers, which may increase adherence to device use in the long-term by matching patients' preferences with the functionalities of different devices.

Second, albeit only mentioned sparingly in included articles, an offloading device recommendation may depend on adequate access to materials and insurance coverage. While podiatrists and other health care providers might wish to adapt and tailor offloading device recommendations to patients' preferences, they may be unable to do so if they do not have access to different devices in their health service organization or through insurance coverage. As a result, insurance coverage should seek flexibility and diversity so offloading reaches a greater number of patients by matching their preferences.

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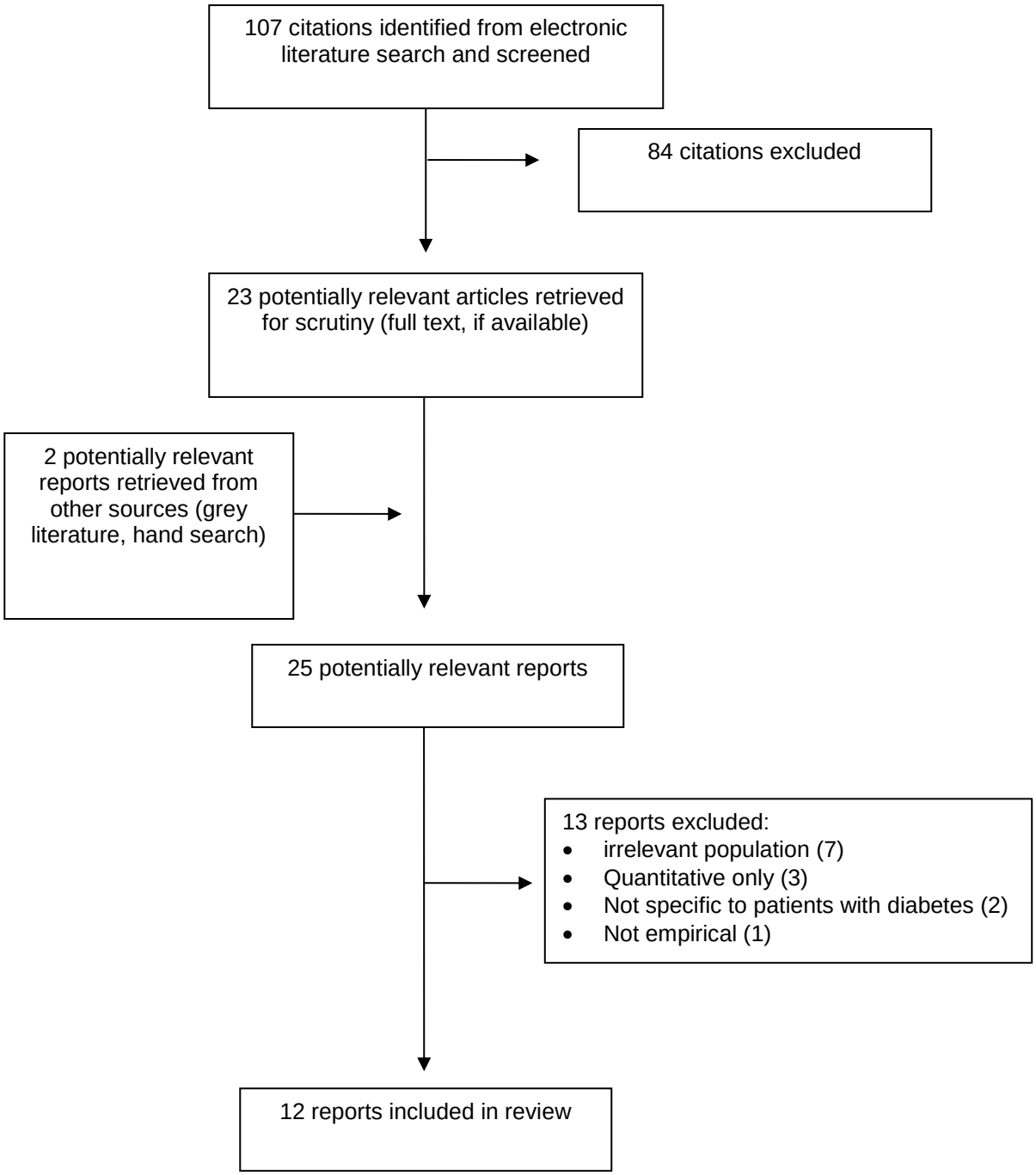
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 1: Characteristics of Included Publications

First Author, Publication Year, Country	Study Design - Analytic Approach[1]	Study Objectives	Inclusion Criteria	Data Collection Strategy
Formosa, 2020, Malta	Qualitative – phenomenology	Explore the reasons for current adherence to prescribed stock footwear amongst patients living with type 2 diabetes	Patients with type 2 diabetes mellitus who were prescribed footwear for at least six months for foot deformities or amputation or ulceration	Semi-structured interviews
Macdonald, 2019, Australia	Mixed-methods – thematic analysis	Determine a model of psychosocial factors that best predict participant intention to use smart insoles	Patients with diabetes and currently engaged with any particular type of offloading technology	Focus groups
McLean, 2019, Australia	Mixed-methods – NR	Evaluate the impact of podiatrist-led casting service model within a rural and regional setting	NR	Focus groups
Tan, 2019, Singapore	Qualitative – phenomenology	Explore the lived experience of participants with diabetes using prescription footwear	Patients with diabetes who have been prescribed off-the-shelf prescription footwear. Patients wearing temporary wound sandals were excluded	Semi-structured interviews
van netten, 2019, Australia	Qualitative – framework analysis	Explore the reasons for (non-)adherence to self-care among people with diabetic foot ulcers as well as barriers and solutions to improving self-care adherence	Patients with type 1 or 2 diabetes mellitus and a foot ulcer	Semi-structured interviews
Health Quality Ontario, 2017, Canada	Qualitative – grounded theory	Explore the underlying values, needs, impacts, and preferences of those who have lived experience with the treatment of diabetic foot ulcers	Patients with diabetic foot ulcers who use the following offloading devices: total contact casting, removable cast walkers, and irremovable cast walkers	Semi-structured interviews
Hjelm, 2016, Sweden	Qualitative – qualitative description	Describe beliefs about health and illness among foreign-born people with diabetic foot ulcers that might affect self-reported self-care and health care seeking	Patients with a diagnosis of diabetes for over one year who presented to a clinic for a foot ulcer	Semi-structured interviews
Campbell, 2015, Canada	Mixed-methods – NR	Compare outcomes, nursing visits, and nursing visit costs for 40 patients with heel ulcers treated at a clinic with a non-removable padded heel dressing	Patients with a heel ulcer from diabetes, peripheral artery disease, and other neuropathies who were treated with padded heel dressing	Qualitative comments from an electronic health record system
Madden, 2015,	Qualitative – framework analysis	Explore the impact of footwear, bandaging, and hosiery interventions in the everyday	Patients with lower limb ulcers: venous leg ulcers, injecting drug use, and diabetic foot ulcers	Semi-structured interviews

First Author, Publication Year, Country	Study Design - Analytic Approach[1]	Study Objectives	Inclusion Criteria	Data Collection Strategy
United Kingdom		lives of women and men undergoing treatment for chronic, complex wounds		
Paton, 2014, United Kingdom	Qualitative – phenomenology	Explore the psychological influences and personal experiences behind the daily footwear selection of individuals with diabetes and neuropathy	Patients with diabetes or diabetic neuropathy who have been supplied with therapeutic insoles and footwear at least six months before contact	Semi-structured interviews
Raspovic, 2014, Australia	Mixed-methods – content analysis	Investigate offloading practices for diabetes related to plantar neuropathic ulcers	Podiatrists who routinely managed complex and chronic high-risk foot complications such as foot ulceration	Semi-structured interviews
Paton, 2013, United Kingdom	Qualitative – framework analysis	Explore the experiences and views of people with diabetes and neuropathy who have recently fallen	Patients with diabetes or diabetic neuropathy who have been supplied with therapeutic insoles and footwear at least six months before contact	Semi-structured interviews

NR = not reported

[1] The analytic approach for the qualitative portion is only shown here for mixed- or multiple-method studies

Appendix 3: Characteristics of Study Participants

Table 2: Characteristics of Study Participants

First Author, Publication Year, Country	Sample Size	Sex (% male)	Mean Age or age range in years	Type of Offloading Device
Formosa, 2020, Malta	12 patients with diabetes	50.0%	NR	NR
Macdonald, 2019, Australia	53 patients with diabetes	NR	NR	Smart shoe insole
McLean, 2019, Australia	NR number of podiatrists	69.6%	Range: 47-71	Total contact cast and instant total contact cast
Tan, 2019, Singapore	8 patients with diabetes	87.5%	NR	NR
van netten, 2019, Australia	11 patients with diabetes	90.9%	Range: 43-74	NR
Health Quality Ontario, 2017, Canada	16 patients with diabetes	NR	NR	Total contact cast, removable cast walker, irremovable cast walker
Hjelm, 2016, Sweden	26 patients with diabetes	76.9%	Range: 7-60	NR
Campbell, 2015, Canada	28 patients with diabetes	NR	Range: 25-95	Padded heel dressing
Madden, 2015, United Kingdom	19 patients with venous leg ulcer, ulcer from injecting drug use, or diabetic foot ulcer (NR number of patients with diabetes)	42.1%	Range: 21-97	NR
Paton, 2014, United Kingdom	4 patients with diabetes	50.0%	Range: 58-84	Insole
Raspovic, 2014, Australia	16 patients with diabetes	NR	NR	Non-removable devices
Paton, 2013, United Kingdom	36 podiatrists	81.3%	Range: 44-83	Insole

NR = not reported

Appendix 4: Critical Appraisal of Included Studies

Table 3: Strengths and Limitations of Included Studies

Strengths	Limitations
Formosa, 2020	
• Identifies the qualitative analytic approach • Identifies research questions or objectives clearly • Specifies “footwear” used by patients with diabetes	• Does not provide a justification for choosing study design or analytic approach • Lack sufficient detail on selection and recruitment of participants, data collection methods, and data analysis processes • No considerations on quality or rigor of the study
Macdonald, 2019	
• Identifies and justifies the chosen qualitative study design or analytic approach • Identifies research questions or objectives clearly • Sufficient detail on data collection methods • Provides adequate discussion of the relationship between qualitative and quantitative strands of study • Specifies offloading device	• Lack sufficient detail on selection and recruitment of participants, and data analysis processes • No considerations on quality or rigor of the study • Does not provide eligibility criteria for the qualitative portion of the mixed-methods study
McLean, 2019	
• Identifies research questions or objectives clearly • Specifies offloading device	• Does not identify the study design or analytic approach • Lack sufficient detail on selection and recruitment of participants, data collection methods, and data analysis processes • No considerations on quality or rigor of the study • No discussion on the relationship between the qualitative and quantitative strands of the study
Tan, 2019	
• Identifies research questions or objectives clearly • Identifies and justifies the chosen qualitative study design or analytic approach • Sufficient detail on selection and recruitment of participants, data collection methods, and data analysis processes • Specifies offloading device	• No considerations on quality or rigor of the study
van netten, 2019	
• Identifies the qualitative study design or analytic approach • Sufficient detail on selection and recruitment of participants, data collection methods, and data analysis processes • Specifies self-care practices among patients with diabetes, including offloading device	• Does not provide a justification for choosing study design or analytic approach • Does not identify research questions or objectives clearly • No considerations on quality or rigor of the study
Health Quality Ontario, 2017	
• Identifies research questions or objectives clearly • Identifies and justifies the chosen qualitative study design or analytic approach	• No considerations on quality or rigor of the study

Strengths	Limitations
• Sufficient detail on selection and recruitment of participants, data collection methods, and data analysis processes • Specifies offloading device	
Hjelm, 2016	
• Identifies research questions or objectives clearly • Identifies a theoretical framework • Identifies the qualitative study design or analytic approach • Sufficient detail on selection and recruitment of participants, data collection methods, and data analysis process • Specifies “footwear” used by patients with diabetes	• Does not provide a justification for choosing study design or analytic approach • No considerations on quality or rigor of the study • Not specific to an offloading device or diabetes
Campbell, 2015	
• Identifies research questions or objectives clearly • Sufficient detail on selection and recruitment of participants • Specifies offloading device	• Does not identify the study design or analytic approach • Lack sufficient detail on data collection methods and data analysis processes • No considerations on quality or rigor of the study • No discussion on the relationship between the qualitative and quantitative strands of the study
Madden, 2015	
• Identifies research questions or objectives clearly • Identifies and justifies the chosen qualitative study design or analytic approach • Sufficient detail on data collection methods and data analysis approaches • Considers issues with study quality and rigor	• Lack sufficient detail on selection and recruitment of participants • Not specific to an offloading device or diabetes
Paton, 2014	
• Identifies research questions or objectives clearly • Identifies and justifies the chosen qualitative study design or analytic approach • Sufficient detail on selection and recruitment of participants, data collection methods, and data analysis approaches • Considers issues with study quality and rigor • Specifies offloading device	• Unclear of the relationship between this study and another included in this review by the same authors [28]
Raspovic, 2014	
• Identifies research questions or objectives clearly • Identifies the qualitative study design or analytic approach • Sufficient detail on selection and recruitment of participants, and data collection methods • Specifies offloading device	• Does not provide a justification for choosing study design or analytic approach • No considerations on quality or rigor of the study • Lack sufficient detail on data analysis processes
Paton, 2013	
• Identifies research questions or objectives clearly	• Lack sufficient detail on data analysis processes • No considerations on quality or rigor of the study

Strengths	Limitations
• Identifies and justifies the chosen qualitative study design or analytic approach • Sufficient detail on selection and recruitment of participants, and data collection methods • Specifies offloading device	• Unclear of the relationship between this study and another included in this review by the same authors [25]