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Offloading Devices for Diabetic Foot Ulcers

Health Technology Assessment

The Health Technology Assessment Unit, University of Calgary

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Abbreviations

AGE	Advanced glycation end
AHS	Alberta Health Services
AISH	Assured Income for the Severely Handicapped
ABI	Ankle-Brachial Index Test
ATL	Achilles Tendon Lengthening
BC	British Columbia
BIA	Budget impact analysis
BTCC	Bivalved total contact cast
CAD	Canadian dollar
CADTH	Canadian Agency for Drugs and Technologies in Health
CEA	Cost-effectiveness analysis
CI	Confidence interval
CLI	Critical limb ischemia
CUA	Cost-utility analysis
DFCCP	Diabetes Foot Care Clinical Pathway
DFU	Diabetic foot ulcer
DM	Diabetes mellitus
ET	Enterostomal therapy nurse
FOS	Forefoot offloading shoes
GP	General practitioner
HTA	Health technology assessment
HQO	Health Quality Ontario
HRQoL	Health-Related Quality of Life
ICER	Incremental cost-effectiveness ratio
ICW	Irremovable cast walker
ITT	Intention to treat
iTCC	Instant total contact casting
LIM	Low income measure

NIHB	Non-insured health benefits
NP	Nurse practitioner
NR	Not reported
OH	Ohio
OT	Occupational therapist
PAD	Peripheral arterial disease
PN	Peripheral neuropathy
PP	Per protocol
PT	Physiotherapist
RCT	Randomized controlled trial
RCW	Removable cast walker
RN	Registered Nurse
SF-36	36-item Short Form
SIRS	Systemic inflammatory response syndrome
TCC	Total contact casting
UK	United Kingdom
USA	United States of America

1 Executive Summary

This report presents the findings and conclusions of a provincial health technology assessment on total contact casting, removable cast walkers and irremovable cast walkers in comparison to each other, and in comparison to other offloading devices and non-offloading devices for patients with diabetic neuropathic foot ulcers. The policy question to be address by this review is: "How do total contact casts, removable cast walkers and irremovable cast walkers compare with each other, other offloading devices and non-offloading devices for patients with diabetic neuropathic foot ulcers, taking into account clinical efficacy, patient and clinical perspectives, cost-effectiveness and budget impact?"

The primary research questions for this health technology assessment were:

1. What is the clinical effectiveness of total contact casting, removable cast walkers, and irremovable cast walkers compared with other offloading devices (including each other) and non-offloading treatments in patients with diabetic neuropathic foot ulcers?
2. What is the cost-effectiveness and budget impact of total contact casting, removable cast walkers, and irremovable cast walkers in treating patients with diabetic neuropathic foot ulcers?

Background:

Diabetic foot ulcers (DFUs) are a common and serious diabetes-related complications arising from chronic hyperglycemia.[1] The prevalence of foot ulcers among persons with diabetes mellitus varies between 4% and 10%,[2,3] with up to 25% of patients with diabetes mellitus likely to develop diabetic foot ulcer in their lifetime.[4] Within BC, there were 2,744 patients diagnosed with a DFU in 2016, and 169 (6%) of those individuals required amputation based on BC administrative data. Similarly in 2019, there were 3,250 people with a DFU, and 182 (6%) of those individuals required amputations.

Treatment for DFU involves a comprehensive care plan including wound debridement, treatment of infection, revascularization procedures when indicated, and pressure offloading. Offloading devices are used to achieve therapeutic success and healing by reducing external pressure, deferring skin pressure, and by protecting the wound site to prevent repetitive trauma.[7]

Offloading device options include total contact casting (TCC), removable cast walker (RCW), irremovable cast walker (ICW), half-shoe, healing sandal, therapeutic footwear, felted foam, and mobility aids.

Methods:

The following methodological approaches were used to gather and synthesize the available evidence:

I. Review of guidelines and best practice recommendations
II. Systematic review of health technology assessments
III. Jurisdictional scan of offloading device use across Canada
IV. Systematic review of clinical efficacy and safety of total contact casts, removable cast walkers and irremovable cast walkers
V. Rapid review of patient experience literature
VI. Patient interviews
VII. Interviews with BC-based health care providers
VIII. Cost-utility analysis
IX. Budget impact analysis and implementation analysis

Key Findings:

Fourteen guidelines were identified. All guidelines suggested using an offloading device to minimize trauma to the active ulcer site. A non-removable knee-high offloading device was most frequently recommended (TCC, or ICW) with many noting that due to forced adherence, non-removable devices may lead to better wound closure. The exception to this is for those with ischemic or infected wounds, for which an irremovable offloading device is contraindicated, RCW is recommended. Canadian guidelines also provided recommendations regarding treatment of DFUs within multidisciplinary clinics or alongside referrals to allied health professionals, along with follow up to ensure proper and timely healing along with subsequent foot screening exams after ulcer healing within the prescribed time frame. Many guidelines describe the need for offloading decisions to consider factors such as the impact on patient lifestyle and occupation, affordability and accessibility, and patient support system.

A survey of Canadian offloading device providers was conducted as part of a jurisdictional scan to understand the integration of offloading devices into the treatment of DFUs across Canada. Responses were received from podiatric surgeons (n=2), a geriatric physician (n=1), a pedorthist (n=1), an orthopedic technologist (n=1), an infectious disease specialist (n=1), a chiropodist and diabetes educator (n=1), a family physician and academic researcher (n=1), an ER and family physician (n=1), and a registered nurse (n=1). Respondents were from the following six provinces: Alberta (n=3), Manitoba (n=2), Ontario (n=2), Prince Edward Island (n=1) Saskatchewan (n=1), and Quebec (n=1). Across Canada, treatment pathways for patients with DFU varies. Survey respondents from Alberta, Manitoba, Ontario and Quebec follow the Wounds Canada best practice recommendations and/or the International Working Group of Diabetic Foot (IWGDF) clinical practice guidelines. Most respondents offer a variety of offloading devices to their patients, all but two providers offer TCC. None of the respondents actively offer ICW.

A systematic review of previous health technology assessments (HTAs) and evidence summaries comparing offloading devices for the treatment of diabetic foot ulcers, including TCC, RCW, and ICW, identified two publications. Both HTAs are Canadian; one conducted by Health Quality Ontario (HQO) and the other by the Canadian Agency for Drugs and Technologies in Health (CADTH). The HTA conducted by HQO included a review of clinical effectiveness, review of economic evaluations, primary economic evaluation, budget impact analysis, and patient interviews. An evidence review conducted by CADTH included reviews of clinical effectiveness and economic evaluations. Both concluded that total contact casts (TCC) or irremovable cast walkers (ICW) were likely to be the most clinically effective and cost-effective option.

The systematic review of clinical effectiveness and safety identified 17 randomized controlled trials (RCT). Of these, eight studies had sufficient data to permit meta-analysis. Meta-analysis was conducted on the number of ulcers healed at three months follow-up, and mean time to ulcer healing. There was no statistically significant difference in the risk ratio of ulcer healing of TCC compared to ICW (95% CI: 0.93 to1.2), or TCC versus RCW (95% CI 0.99 to 1.36). However at 12 weeks, ICWs were 1.4 times more likely to result in ulcer healing than RCWs (95% CI: 1.0 to 1.97) (Table 1). For mean time to healing, there was no statistically significant difference for

TCC versus ICW (95% CI: -0.4 to 0.37), TCC versus RCW (95% CI: -2.48 to 0.55), or ICW versus RCW (95% CI: -1.26 to 0.08).

Table 1. Summary of Meta-analysis

	Comparators	**Pooled Estimate**	**95% Confidence Interval**	**Heterogeneity (I^2)**
Ulcers Healed at 3 months	TCC and ICW	RR: 1.06	0.93 to 1.20	0.0%
	TCC and RCW	RR: 1.16	0.99 to 1.36	0.0%
	ICW and RCW	RR: 1.40*	1.0 to 1.97	54.3%
Mean time to Healing	TCC and ICW	SMD: -0.01	-0.4 to 0.37	0.0%
	TCC and RCW	SMD: -0.96	-2.48 to 0.55	88.0%
	ICW and RCW	SMD: -0.59	-1.26 to 0.08	44.8%

*Statistically significant result ($p<0.05$).
Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; RR: risk ratio; SMD: standard mean difference; TCC: total contact casting

Patient perspectives were captured through a combination of a rapid qualitative literature review and patient interviews. The rapid literature review was conducted by CADTH. From the 12 studies identified in their rapid review, patients and podiatrists identified the following barriers to following treatment advice of offloading devices: mobility and autonomy, device mechanics, perceptions of the device's effectiveness, self-image and restoring social normalcy, device cost, and lack of information. It also identified that additional opportunities for a collaborative discussion between healthcare providers and their patient to allow for shared decision making in choice of offloading device may lead to use of devices as recommended.

Interviews were conducted with eight patients living in BC; analysis of this data was largely consistent with what was found in the rapid review of literature. Broadly, patients reported following treatment recommendations for wearing their offloading device for the initial healing, although some struggled to wear their maintenance devices, which led to re-ulceration. Offloading devices were reported to impact patients' mobility, sleep, ability to shower, were associated with high cost and time-commitment for appointments, and resulted in stigma. Patients who received TCCs shared gratitude and appreciation for the effective treatment allowing the foot ulcer to heal very quickly. Patients reported wishing for more coverage of

offloading devices in BC, as well as more accessibility to certain devices (primarily TCCs), and more education around the seriousness of the condition, options available, and what could happen if they do not wear the device.

Interviewed clinicians reported that based on their clinical experience, BC patients with DFUs are struggling to receive the right care, at the right time, and with the right provider. Cost was reported to be a major barrier to accessing care, with diabetic offloading devices and certain specialists (e.g., podiatrists) not publicly funded in BC and indirect costs incurred from time off work. Diabetic foot ulcers were largely perceived to be a problem resulting from poverty, with social determinants of health contributing the certain groups of patients being more vulnerable than others. Care providers report frustration over this barrier and others, like the lack of access to a range of offloading devices, and lack of time to apply the devices and the lack of time to provide comprehensive care to their patients; these barriers result in high ulcer recurrence rates. Care providers differed in their opinions of where future funding for diabetic foot care in BC should be directed as there was considerable variability in the standard of care reported across the province, but all stressed the need for funding to be focused on preventative care.

A cost-utility analysis was conducted to compare cost and quality adjusted life years (QALYs) between offloading options for the treatment of uninfected diabetic foot ulcers, from the perspective of the publicly funded healthcare system in British Columbia, using a three-month time horizon. In the base-case analysis, ICWs are predicted to result in cost-savings with an incremental cost-effectiveness ratio (ICER) of -$132,295 when compared to no offloading treatment. The ICER for TCCs relative to no offloading treatment was -$119,151 per QALY gained. The ICER for RCW relative to no offloading was dominated as it cost more and resulted in less QALYs than ICWs. When 3-year and 5-year scenario analyses were considered, ICWs and TCCs offered cost-savings when compared to no offloading and RCWs were dominated by ICWs; similar to the results of the base-case analysis. This cost-utility analysis suggests that ICWs and TCCs offer increased benefit and decreased costs for the treatment of uninfected DFUs.

Based on the evidence herein, three implementation scenarios were explored: 1) maintain status quo, 2) income-based funding for offloading treatments, and 3) age-based funding for offloading treatments. Treatments considered for funding are traditional dressings or no offloading (represents the status quo), RCW, ICW, and fiberglass TCC. Each has unique advantages and disadvantages including impact on health and non-health benefits, provincial expenditure, and access equity. A budget impact analysis conducted over a 3-year time horizon predicted that all offloading treatments will result in cost savings relative to the status quo, with the magnitude of cost savings being directly proportional to the number of patients for whom treatment is funded and likelihood of ulcer healing at 3 months.

Conclusions:

Broadly, the evidence herein describes how TCC, RCW, ICW and other offloading devices have benefits and drawbacks in terms of clinical effectiveness, patient tolerance, and cost-effectiveness. Interviewed patients reported wishing for more coverage of offloading devices in BC, as well as more accessibility to certain devices (primarily TCCs). They also described a need for more education around the seriousness of the condition, options available, and what could happen if they do not wear the device. Interviewed clinicians reported that based on their clinical experience, BC patients with DFUs are struggling to receive the right care, at the right time, and with the right provider, with cost of the device and cost to access specialists being the main barrier. Both the cost effectiveness model and budget impact analysis found that funding offloading devices may result in cost-savings and added health benefit. Implementation considerations were assessed for each of the three scenarios modeled by the budget impact analysis. Each scenario has unique advantages and disadvantages including impact on health and non-health benefits, provincial expenditure, and access equity.

2 Purpose of this Health Technology Assessment

The purpose of this HTA is to synthesize the evidence on total contact casts, removable cast walkers and irremovable cast walkers in comparison to each other, and to other offloading and non-offloading devices for treatment of diabetic foot ulcers. This report summarizes the clinical effectiveness and safety literature on total contact casts, removable cast walkers and irremovable cast walkers in comparison to other offloading devices (Figure 1). The current context on the use of these devices in BC and Canada is presented, in the form of patient and clinician interview and a jurisdictional scan, as well as an economic model. Finally, an implementation and budget impact analysis are presented with a range of implementation scenario, each with unique advantages and disadvantages including impact on health and non-health benefits, provincial expenditure and access equity.

Figure 1. Technologies under consideration

3 Research Question and Objectives

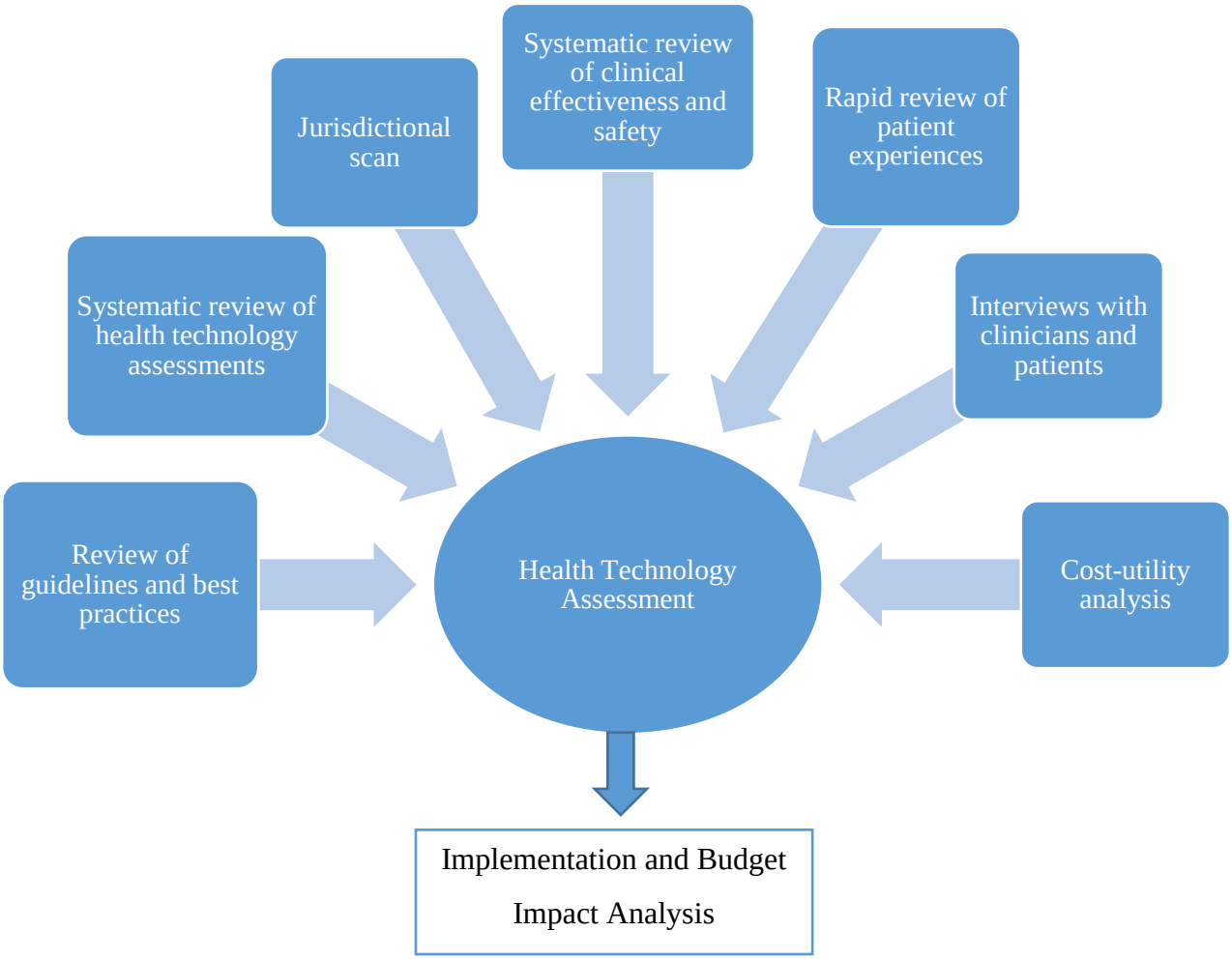
The primary research questions are:

1. What is the clinical effectiveness of total contact casting, removable cast walkers, and irremovable cast walkers compared with other offloading devices (including each other) and non-offloading treatments in patients with diabetic neuropathic foot ulcers?
2. What is the cost-effectiveness and budget impact of total contact casting, removable cast walkers, and irremovable cast walkers in treating patients with diabetic neuropathic foot ulcers?

A variety of methodological approaches were used to gather and synthesize the available evidence in order to address the primary research question (Figure 2). The following methodologies were used:

I. Review of Guidelines for use of offloading devices for DFU
II. Systematic Review of Health Technology Assessments of offloading devices for DFU
III. Jurisdictional Scan of offloading device practices across Canada
IV. Systematic Review of Clinical Effectiveness and Safety of offloading devices for DFU
V. Rapid Review of Patient Perspectives
VI. Patient Interviews
VII. Clinician Interviews
VIII. Cost-effectiveness Analysis
IX. Budget Impact Analysis
X. Implementation Analysis

Figure 2. Summary of Process



4 Background

5.1 Diabetic Foot Ulcers

5.1.1 Overview

Diabetic foot ulcers (DFUs) are a common and serious diabetes-related complications arising from chronic hyperglycemia.[1] Excessive glucose due to uncontrolled diabetes can lead to diabetic peripheral neuropathy (DPN), in particular, in the feet and legs.[5,6] DPN results in nerve damage, numbness, loss of sensation and generalized pain which can lead to delayed discovery and diagnosis of DFU.[5,6] Moreover, diabetes causes vascular disease and may alter nutrient blood supply, with ischemia leading to ulcer proneness. The lack of sensation and decreased metabolic response renders patients unable to respond to repetitive stress and trauma to their plantar tissues, leading to skin damage and wounds.[1] Diabetic patients with concomitant obesity may experience additional trauma to wound site due to the increased load.

5.1.2 Epidemiology

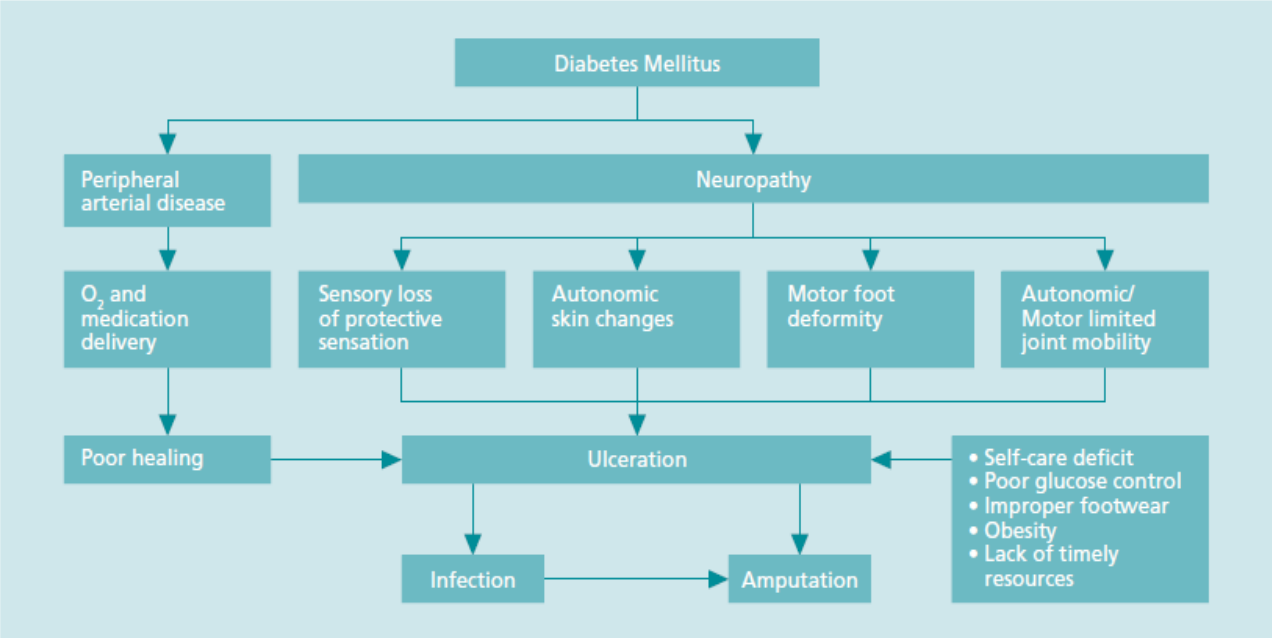
The prevalence of foot ulcers among persons with diabetes mellitus varies between 4% and 10%,[2,3] with up to 25% of patients with diabetes mellitus (DM) likely to develop diabetic foot ulcer in their lifetime.[4] It is more prevalent in males than females and in those with type 2 DM than type 1.[2] A study conducted by Hopkins et al., estimated that in 2011, the national prevalence of diabetic foot ulcers was 75.1 per 100,000 people, equating to an estimated 25,600 cases in Canada.[7] The risk of ulceration is highest among those who have previously had a diabetic foot ulcer; the chance of re-ulceration is 34% within one year of healing an ulcer and 70% within 5-years.[8] Patients with low socioeconomic status are more likely to expereince ulceration, severe foot infections and subsequent amputations.[9] In Canada, foot ulceration and amputation are two to three times more common and occur at a younger age in Indigenous populations.[10]

Diabetes is the leading cause of non-traumatic limb amputation in Canadian adults.[8,11,12] While two thirds of ulcers heal, one third result in amputation due to infection.[5] In 2016, BC administrative data indicated 2,744 patients had a DFU in BC, and approximately 169 (6%) of those individuals required amputation. Similarly in 2019, there were 3,250 patients with DFU and 182 (6%) of those individuals required amputations.

5.1.3 Pathophysiology

The pathogenesis of diabetic foot ulcer is complex, involving a multiplicity of factors including neuropathy, ischemia, foot deformity and higher foot pressures (Figure 3). However, the main etiological factors are neuropathy, ischemia or a combination of both.[13,14]

Figure 3. Pathway to diabetic foot ulcers



Source: Levin et al. 2001[15]

5.1.3.1 Ischemia

Up to 30% of diabetic patients have peripheral arterial disease (PAD),[16,17] characterized by ischemia in the lower extremities, and about half of the patients with diabetic foot ulcer have PAD.[13,18] Purely ischemic ulcers occur only in about 15% of patients with diabetic foot ulcers.[19] The presence of ischemia impairs the normal body response to foot ulcerations, leading to non-healing ulcers because of limited flow of blood, nutrition and oxygen to the wound. This facilitates the progression of infection and promotes tissue break down.[3] In addition to longer healing time, PAD also increases the risk of recurrence and amputation.[13]

5.1.3.2 Neuropathy

Two possible mechanisms have been proposed for the pathogenesis of diabetic neuropathy. These include the Maillard reaction and the blockade of nitric oxide synthesis.[20] The former involves the increase in the non-enzymatic glycation of intracellular proteins resulting in the formation of advanced glycation end (AGE) products, which can alter the properties of the structural proteins[21] of the peripheral nerves, cause the degeneration of the nerves and also impair their regeneration.[22]

The nitric oxide mechanism involves the inhibition of endothelial nitric oxide synthase activation, thereby preventing the production of nitric oxide. Nitric oxide is an endogenous vasodilator and a potent inhibitor of platelet aggregation. It is also a regulator of the expression of proteins involved in atherogenesis[23] in the small vessels supplying the peripheral nerves, including those of the foot.

Peripheral sensory neuropathy is the most common form of neuropathy; it results in insensitivity to pain, thereby eliminating the signals that warn the patient of impending or ongoing tissue trauma. The foot is further exposed to increased and repetitive pressure that results in tissue damage and ulceration.[24] Autonomic neuropathy may increase the risk of dryness, fissuring and infection in the foot due to the loss of sweat and oil gland function.[25] Motor neuropathy causes weakness and atrophy of the intrinsic muscles of the foot which may result in clawing of the toes, plantarflexion of the head of the metatarsals and other anatomic deformities.[24] The anatomic deformity and restriction in joint mobility from motor neuropathy or other structural foot deformities such as Charcot neuroarthropathy, flatfoot, hallux valgus, claw toes and hammer foot leads to ulcer prone pressure points and calluses on the sole of the foot, particularly on the forefoot or the surfaces of bony prominences.[24,26] Trauma is required to facilitate tissue breakdown. This can be intrinsic, such as from recurrent pressure and/or callus, or extrinsic from ill-fitting footwear.[14]

5.1.4 Risk Factors for Diabetic Foot Ulcers

Risk factors for DFUs include:

- PAD causing critical limb ischemia (CLI)[27,28]

- Combination of diabetic neuropathy, deformity, callus, and elevated peak skin pressure[27-29]
- Penetrating trauma[27,30]
- Ill-fitting shoes, or friction induced skin trauma[27,29,30]
- History of previous ulcers[5,6,31,32]
- Poor glycemic control[26]
- Cigarette smoking[33]
- Male gender[33]
- Social factors e.g., low socioeconomic status, lack of access to healthcare services, and poor education[26]

5.1.5 Clinical Features

Neuropathic ulcers are commonly seen under the metatarsal heads or the toes on the sole of the feet.[34,35] They are usually preceded by calluses, which can compress the underlying soft tissue.[35] An early indication of ulceration is often a layer of whitish, macerated, moist tissue found under the surface of a callus. Tissue necrosis occur if calluses are not quickly removed and small, serous fluid cavities with blister-like appearance begins to develop.[35] The neuropathic foot is warm with a palpable pulse (Table 2). Autonomic involvement diminishes sweating, causing dry skin that may likely crack.[35]

Superficial blisters are the first signs of an ischemic ulcer. These are usually secondary to friction.[35,36] They subsequently develop into shallow ulcers, with pale or yellowish granulation tissue at their base.[35] Ischemic DFU tend not to develop on the plantar surface of the foot because the blood supply to this area is relatively better preserved.[19] Ulcerations are however common on the tip of the toes and nail edges,[6,30] with associated pain at rest.[34]

Neuroischemic DFUs are the combined effect of diabetic neuropathy and ischemia.[35] Neuroischemic ulcers are commonly seen on the medial surface of the first metatarsophalangeal joint, over the lateral aspect of the fifth metatarsophalangeal joint[35,36] on the tip of the toes and under the toe nails.[35] Unlike the neuropathic diabetic foot, the neuroischemic foot is pulseless and cold (Table 2), and the overlying skin is thin, shiny, and hairless.[35]

Table 2. Diabetic Foot Ulcers

Feature	Neuropathic	Ischemic	Neuroischemic
Sensation	Sensory loss	Pain	Degree of sensory loss
Callus/necrosis	Callus present and often thick	Necrosis common	Minimal callus; prone to necrosis
Wound bed	Pink and granulating, surrounded by callus	Pale and sloughy with Poor granulation	Poor granulation
Foot temperature and pulses	Warm with bounding pulses	Cool with absent pulses	Cool with absent pulses
Other	Dry skin and fissuring	Delayed healing	High risk of infection
Typical location	Weight-bearing areas of the foot, such as metatarsal heads, the heel and over the dorsum of clawed toes	Tips of toes, nail edges and between the toes and lateral borders of the foot	Margins of the foot and toes
Prevalence	35%	15%	50%

Source: Wounds International[6]

5.1.6 Classification of Diabetic Foot Ulcers

A number of classification systems exist for diagnosing DFUs, including Wagner, Meggitt-Wagner, University of Texas, PEDIS, and SINBAD (Table 3). Before wound healing can be facilitated, a preliminary evaluation of the foot ulcer starts with assessment of arterial blood supply to ensure adequacy of perfusion.[37]

Table 3. Classification Systems of Diabetic Foot Ulcers

System	Characteristics
Wagner	Assess ulcer depth along with the presence of gangrene and loss of perfusion using six grades (0-5)
Meggitt-Wagner	Assess ulcers into three categories: infective, non-infective and mixed
University of Texas	Assesses ulcers depth, presence of infection and presence of signs of lower extremity ischemia using a matrix of four grades combined with four stages
PEDIS	Assesses perfusion, extent (size), depth (tissue loss), infection and sensation (neuropathy) using four grades (1-4)
SINBAD	Assesses site, ischemia, neuropathy, bacterial infection and depth; uses a scoring system to help predict outcomes and enable comparisons between different settings and countries

Abbreviations: PEDIS: perfusion, extent, depth infection and sensation; SINBAD: site, ischemia, neuropathy, bacterial infection and depth
Source: Wounds International[6]

5.1.6.1 Meggitt-Wagner Classification System and Wagner Classification System

Meggitt first described this classification system in 1976 and it was adjusted and popularized by Wagner in 1981 and is now a well-established system.[38] Meggitt's original system assessed ulcers into three categories: infective, non-infective and mixed.[6] The Meggitt-Wagner system assesses the wound ulcer depth and appearance using the following grades: grade 0 (pre or postulcerative lesion), grade 1 (partial/full thickness ulcer), grade 2 (probing to tendon or capsule), grade 3 (deep with osteitis), grade 4 (partial foot gangrene), and grade 5 (whole foot gangrene) (Table 4).[38,39] This system does not fully address infection and ischemia.[39]

Table 4. Meggitt-Wagner Ulcer Classification System[38,39]

Wagner Grade	Description
Grade 0	Intact skin
Grade 1	Superficial diabetic ulcer

Grade 2	Ulcer extension involving ligament, tendon, joint capsule, or fascia with no abscess or osteomyelitis
Grade 3	Deep ulcer with abscess or osteomyelitis
Grade 4	Gangrene to portion of forefoot
Grade 5	Extensive gangrene of foot

5.1.6.2 University of Texas Classification System

The University of Texas system is another well-established system that assesses ulcer depth, the presence of infection and the presence of clinical signs of lower-extremity ischemia.[40] This system uses a matrix, with grade on the horizontal axis and stage on the vertical axis (Table 5). The grades of the UT system are as follows: grade 0 (pre- or postulcerative site that has healed), grade 1 (superficial wound not involving tendon, capsule, or bone), grade 2 (wound penetrating to tendon or capsule), and grade 3 (wound penetrating bone or joint).[40] Within each wound grade there are four stages: clean wounds (stage A), nonischemic infected wounds (stage B), ischemic noninfected wounds (stage C), and ischemic infected wounds (stage D).[40]

Table 5. University of Texas Classification System[40]

Stage/Grade	Grade 0	Grade 1	Grade 2	Grade 3
Stage A	Pre- or post-ulcerative lesion completely epithelialized	Superficial wound, not involving tendon, capsule or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
Stage B	With infection	With infection	With infection	With infection
Stage C	With ischemia	With ischemia	With ischemia	With ischemia
Stage D	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia

5.1.6.3 PEDIS Classification System

This system is developed by the International Working Group on the Diabetic Foot (IWGDF), it is user-friendly for practitioners with a lower level of experience with diabetic foot management and with clear definitions and few categories.[41] Like the S(AD) SAD (Size (Area, Depth), Sepsis Arteriopathy, and Denervation) classification system, it uses the same five components: perfusion, extent, depth, infection, and sensation, and does not include ulcer location (Table 6).[41] Overall score is determined by adding the five separate categories to a maximum score of 12.[41]

Table 6. PEDIS Classification System[41]

Grade	Perfusion	Extent	Depth	Infection	Sensation	Score
1	No PAD	Skin Intact	Skin Intact	None	No Loss	0
2	PAD, No CLI	<1 cm^2	Superficial	Surface	Loss	1
3	CLI	1-3 cm^2	Fascia, Muscle, Tendon	Abscess, Fasciitis, Septic arthritis		2
4		>3 cm^2	Bone or Joint	SIRS		3

Abbreviations: CLI: critical limb ischemia; PAD: peripheral arterial disease; SIRS: systemic inflammatory response syndrome

5.1.6.4 SINBAD Classification System

The SINBAD system is a simplified version of the S(AD) SAD classification system. It includes ulcer site, as data suggests this might be an important determinant of outcome.[42] The SINBAD system uses five clinical features (site area, ischemia, neuropathy, bacterial infection, and depth), which are graded as present (0) or absent (1), resulting in a maximum score of 6 (Table 7).[42]

Table 7. SINBAD Classification System[42]

Category	Site	Score
Site	Forefoot	0
	Midfoot and hindfoot	1

Ischemia	Pedal blood flow intact: at least one palpable pulse	0
	Clinical evidence of reduced pedal flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial Infection	None	0
	Present	1
Area	Ulcer <1 cm^2	0
	Ulcer ≥1 cm^2	1
Depth	Ulcer confined to skin and subcuntaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1

5.1.7 Complications of Diabetic Foot Ulcers

5.1.7.1 Soft tissue abnormalities

These are usually consequences of infection and may include: soft tissue edema, cellulitis, abscess, sinus tracts, tenosynovitis, joint effusions, and arthritis. It is important to distinguish between these because their management are different.[14]

5.1.7.2 Osteomyelitis

Osteomyelitis is the result of non-healing ulcers, it is the consequence of a soft tissue infection that spreads into the bone, involving the cortex first and then the marrow.[13] Osteomyelitis can affect any bone but most frequently the bones of the forefoot (90%) followed by the midfoot (5%) and hindfoot (5%).[13] All ulcers exposing the bone and 82% of moderately deep ulcers have features of osteomyelitis on bone biopsy.[14]

5.1.7.3 Amputation

Amputation is a consequence of failure to manage DFUs, which may be necessary in patients with soft tissue necrosis, osteomyelitis, uncontrollable infection, or intractable pain.[14,43]

5.1.7.4 Death

Patients with DFUs undergoing amputation results in increased mortality rates.[37]

5.1.8 Treatment

The treatment of DFUs should be part of a comprehensive care plan that includes debridement of the wound, treatment of infection, revascularization procedures when indicated, and pressure offloading.

5.1.8.1 Debridement

Debridement involves the removal of necrotic and non-viable ulcer tissue in order to improve healing, by facilitating the formation of granulation tissue. It should be done as often as necessary and can be achieved surgically, enzymatically, mechanically, biologically, and by autolysis.[26] Surgical debridement using a scalpel, the sharp method, is the quickest and most efficient way of removing necrotic tissue. A successful debridement is marked by a healthy bleeding ulcer bed.[35]

5.1.8.2 Wound dressing

After debridement, clinicians should base dressing selection on the wound's location, size and depth, amount of exudate, presence of infection or necrosis and the condition of the surrounding tissue to maintain a moist wound bed.[5]

5.1.8.3 Hyperbaric Oxygen Therapy

Hyperbaric oxygen therapy is designed to support and promote the natural phases of wound healing by increasing the amount of oxygen to the tissue at the site of the DFU.[44] The clinical and cost effectiveness of standard wound care and hyperbaric oxygen therapy in comparison to standard wound care alone is unknown.[44,45]

5.1.8.4 Infection control

Infection is a common feature of DFUs. Although clinical signs of infection such as redness, warmth, tenderness, edema and discharge might be visible[3], these signs may be subtle in early

cases, because of impairment in the inflammatory response. At the sign of systemic infection, deep swab and tissue samples should be sent for culture to guide the selection of antibiotics.[35]

5.1.8.5 Revascularization

Persistent non-healing ischemic ulcers despite optimum treatment may require duplex ultrasound and angiography, which may show areas of stenosis or occlusions that may benefit from angioplasty or arterial bypass.[35]

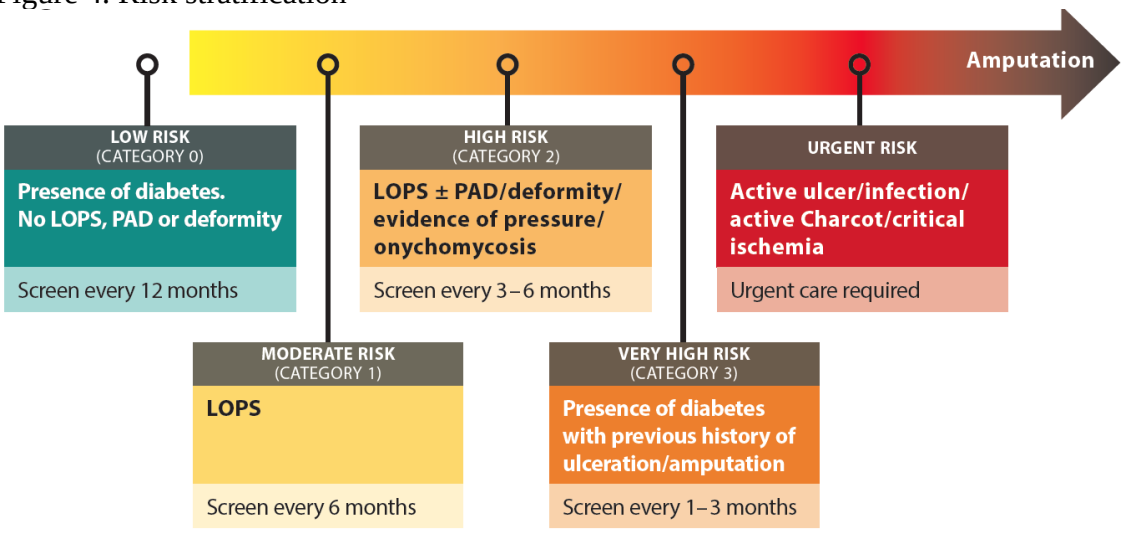
5.1.8.6 Pressure offloading

Off-loading facilitates the healing of plantar ulcers by relieving the ulcers of sustained pressure. Pressure offloading methods include, total contact casting (TCC), removable and irremovable cast walkers, half shoes and felted foam dressing.

5.1.8.7 Education

After treating DFUs, prevention strategies should be discussed. An individualized patient education plan that engages the patient, family, and other caregivers should include managing comorbidities, assessing future DFUs risk based on health status (Figure 4), and exploring potential barriers to adherence.[21] The importance of daily at home foot and shoe checks alongside professional foot checks should also be reiterated, the frequency of which is dependent on DFU risk status.[21] Certain offloading device like specialty shoes may also be recommended for preventative measures. Optimizing tight glycemic control during patient education is assumed to prevent or reduce DFU, however a 2016 review identified this as a gap in knowledge and future research is necessary to determine its effectiveness.[46]

Figure 4. Risk stratification



Source: International Working Group on the Diabetic Foot[2]

Abbreviations: LOPS: loss of protective sensation; PAD: peripheral arterial disease

5.2 Offloading Devices

5.2.1 Technology Overview

Offloading devices are used to achieve therapeutic success and healing by reducing external pressure, deferring skin pressure, and by protecting the wound site to prevent repetitive trauma.[7] In order to reach acceptable healing rates, the appropriate device may be based on a combination of mechanical protection, patient need, and adherence (Table 8).

Table 8. Offloading Devices

Fiberglass Total Contact Casting[47]	Removable Cast Walkers[47]	Irremovable Cast Walkers[47]
 Half-Shoe[48]	 Healing Sandal[49]	 Therapeutic Footwear[50]

5.2.1.1 Fiberglass Total Contact Casting

TCC are custom made non-removable casts that are applied by a knowledgeable healthcare professional. By extending from the distal toes, across the bony prominences of the metatarsal heads and bony midfoot, and beyond the back of the heel, a TCC takes the direct forces that would be applied to any singular site and distributes them across the cast length.[2,3,29] By transferring direct force pressure up the posterior cast wall, wounds are preserved from direct trauma, preventing the mechanism that initiated ulcerative development.[2,3,29] TCC needs to be applied and changed every 1 to 2 weeks to prevent skin lesions from worsening, additional tissue injury, and prevent soft-tissue infection.[2,29] TCC does not permit frequent wound inspections or dressing changes and therefore substantial wound seepage is a contraindication for TCC.[29] It is also contraindicated in the presence of untreated ischemia and infection or osteomyelitis, and in patients with severe PAD.[2,3,29] There are four fiberglass TCC system options: TCC-EZ, TrueKAST, BSN Cutimed and M-Medical. TCC-EZ offers a one-piece, roll-on, woven design that results in an easier application process of under 10 min. TrueKast has a built in saw for removal. BSN Cutimed and M-Medical are both a traditional system, one utilizes BSN cast tape and the other has patented padding protection to prevent lesions.

5.2.1.2 Removable Cast Walkers

Removable cast walkers (RCW) are removable casts with a protective inner sole and a rocker bottom sole that keeps the ankle at a 90-degree angle. They are lightweight with a semi-rigid shell that helps support the limb whilst also providing protection. The foot base is wide enough to allow room for dressings. The removability allows patients or clinical staff to provide wound care with rapid application and removal.[29] In some RCWs, overlapping air cells provide intermittent pneumatic compression for edema reduction while others have additional layers of foam or other soft materials to offer total contact.[20] However, RCWs are not custom-made, therefore they may not fit all patients including those with shorter legs, wide feet, or severe deformities.[20] Patient adherence in wearing this device is necessary for healing.[20]

A Scotchcast boot is one example of a RCW. Scotchcast is a substitute for plaster, resulting in a lighter-weight modality. The Scotchcast boot is a well-padded cast cut away by the ankle and made either removable or nonremovable by cutting away the cast over the dorsum of the foot.[29] A closure is made, consisting of padding and tape with fabric hook and loop fastener straps.[29] Windows are cut over the ulcers as needed, and a removable heel cap of fiberglass is added for large heel ulcers.[29] The boot is worn with a cast sandal to increase patient modality while still protecting the ulcer from any pressure.[29]

5.2.1.3 Irremovable Cast Walkers/Instant Total Contact Cast

Irremovable cast walkers (ICW), also known as an instant total contact cast (iTCC) are hybrid devices that utilizes the frame of an RCW with the semi-permanent binding of a TCC.[20] By wrapping composite fibers such as fiberglass or layers of cohesive tape around an RCW, it has the benefit from the better-tolerated offloading capacity of an RCW combined with total adherence of a TCC.[20] This device allows for frequent wound inspection for patient with severe ischemia, as it can be removed more easily and reapplied.[20]

5.2.1.4 Half shoe

Half-shoes minimize reliance on the forefoot while allowing a fully functional heel-midfoot and toe-off gait pattern.[29] They feature a custom-molded above-ankle brace with a rigid, rocker-bottom sole.[20] The anterior part of the shoe is cut out leaving the heel and the midfoot as the only

weight-bearing surfaces.[20] This custom device requires time and experience to be fabricated to suit patient's needs but are inexpensive and easy to apply.[29]

5.2.1.5 Healing Sandal

A rigid rocker can be applied to the sole of a sandal to provide a greater distribution of metatarsal head pressures as an offloading option. The device is lightweight, stable, and reusable, however time and experience are needed to produce the rigid-sole rocker design and other modifications to suit patient's needs.[29] A device known as MABAL shoe has been introduced, that integrates the qualities of a healing sandal and RCWs by providing more contact with the foot.[20,29] A Mabal cast shoe is another removable fiberglass combi-cast shoe existing of minimal padding with a rigid sole allowing for total contact of the entire plantar surface.[20] A soft cast part extends to just below the ankle, leaving the ankle mobile.[20] A plastic roller sandal is worn underneath the shoe to facilitate walking.[20]

5.2.1.6 Therapeutic footwear/Orthotics (depth-inlay shoes)

Depth inlay shoe are commonly prescribed to diabetic patients after development of ulceration in an effort to reduce recurrence or the severity of recurrence.[29] Ill-fitting footwear is identified as a risk factor therefore properly fitting footwear is crucial.[20] Specifications for properly fitting footwear should include the inside of the shoe being not too tight or too loose and should only be 1-2cm longer than the foot.[20] The internal width should equal the widest part of the foot and the height should allow enough room for all the toes.[20] Custom-made footwear can be made if conventional shoes do not meet those requirements, custom-made insoles or a toe orthosis can also be added. All these devices work to contour the individual foot in a multi-layer construction and accommodate any deformities while relieving pressure over at-risk sites on the plantar and dorsal surfaces of the foot.[20] This footwear can also be worn to prevent first-time foot ulcers.[20]

5.2.1.7 Felted foam

A bilayered felted foam pad is fixed over the plantar aspect of the foot that corresponds to the ulcer site.[29] This offloading method is only recommended if other forms of biomechanical relief are not available and is recommended to be used in combination with appropriate footwear.[20,30,31]

5.2.1.8 Crutches, canes, walkers, wheelchairs

These assistive devices can help offload a foot to promote healing in the diabetic wound. However, they require upper body strength and power.[29] These devices do not have forced adherence, and therefore, effectiveness of offloading would depend on consistency of use.[20,29] Another disadvantage is that assistive devices can place the contralateral limb at risk for ulceration by increasing pressure to the unaffected side.[29] Some patients utilize these devices to assist with immobilizing ambulatory modalities like TCC.[20] These devices can also be used to help with the gradual resumption of weight-bearing upon return to normalcy.[20]

5.2.1.9 Surgical

Surgical offloading can be used as a method of addressing diabetic foot complications when conservative treatment fails. Achilles tendon lengthening (ATL), joint arthroplasty, single or pan metatarsal head resection, or osteotomy can support healing and prevent a recurrent foot ulcer.[29] Other procedures such as exotectomy in combination with tendon lengthening are useful to relieve bony pressure by reducing forefoot pressure and improving the alignment of the ankle and rear foot to the mid foot and fore foot.[2]

5 Review of Clinical Practice Guidelines

Summary

- Fourteen guidelines were identified, from Canada (n=6), America (n=2), Europe (n=2), and international (n=4)
- All guidelines suggested use of an offloading device to minimize trauma to the active ulcer site.
- A knee high offloading device was most frequently recommended; the exception to this is for those with ischemic or infected wounds. All Canadian guidelines recommend not using TCC for patients with infected or ischemic wounds
- Many guidelines describe the need for offloading decisions to consider factors such as the impact on patient lifestyle and occupation, affordability and accessibility, and patient support system.
- Due to the complex nature of DFUs, guidelines describe how a coordinated and multidisciplinary team are best suited to meet needs of a patient.

5.1 Purpose

To synthesize the current guidelines and best practice recommendations regarding the use of offloading devices for diabetic foot ulcers.

5.2 Methods

5.2.1 *Search Strategy*

Two methodologies were employed to ensure all relevant literature was captured: a systematic review of databases, and a grey literature review. The systematic database search was completed by searching Medline, Embase, Cochrane Central Register of Controlled Trials, Cochrane database of systematic reviews, CINAHL, and Web of Science from inception until May 4th, 2020. Terms aimed to capture the technologies of interest, such as “TCC,” “walkers,” “casts,” “aircast,” or “boot” were combined with the Boolean Operator “or.” These searches were combined with terms to indicate the condition of interest, such as “wound healing” or “ulcer.” Terms were searched as text words in titles and abstracts or as subject headings (e.g. MeSH). The search strategy was developed by a research librarian, and PRESS reviewed by another research librarian.[51] The full search strategy is reported in Appendix B.

The database search was supplemented by a grey literature search guided by the Canadian Agency for Drugs and Technologies in Health's (CADTH) "Grey Matters" document. Grey literature and the websites of known HTA organizations, as well as agencies that produce guidelines related to diabetes were searched using terms such as "offloading," "ulcer," "diabetes," "total contact cast," and "cast walker."

5.2.2 *Literature Selection*

Abstracts identified through database searching were screened in duplicate; all abstracts included at this stage by either reviewer proceeded to full-text review. Full-text publications were screened in duplicate. Any discrepancies between reviewers' inclusions were resolved through discussion between reviewers. Publications were excluded if they did not meet the inclusion criteria (Table 9) or if the study was not available in English or French. Publications available as abstracts only were included if they met the inclusion criteria otherwise.

Table 9: Inclusion and Exclusion Criteria for Guideline Review

Inclusion Criteria	**Exclusion Criteria**
• Clinical practice guideline offloading devices for diabetic foot ulcers • English or French Language only	• Not a clinical practice guideline • Not total contact casts, removable cast walkers, or irremovable cast walkers for the treatment of diabetic foot ulcers • Not for diabetic foot ulcers • Not available in English or French

5.2.3 *Data Extraction*

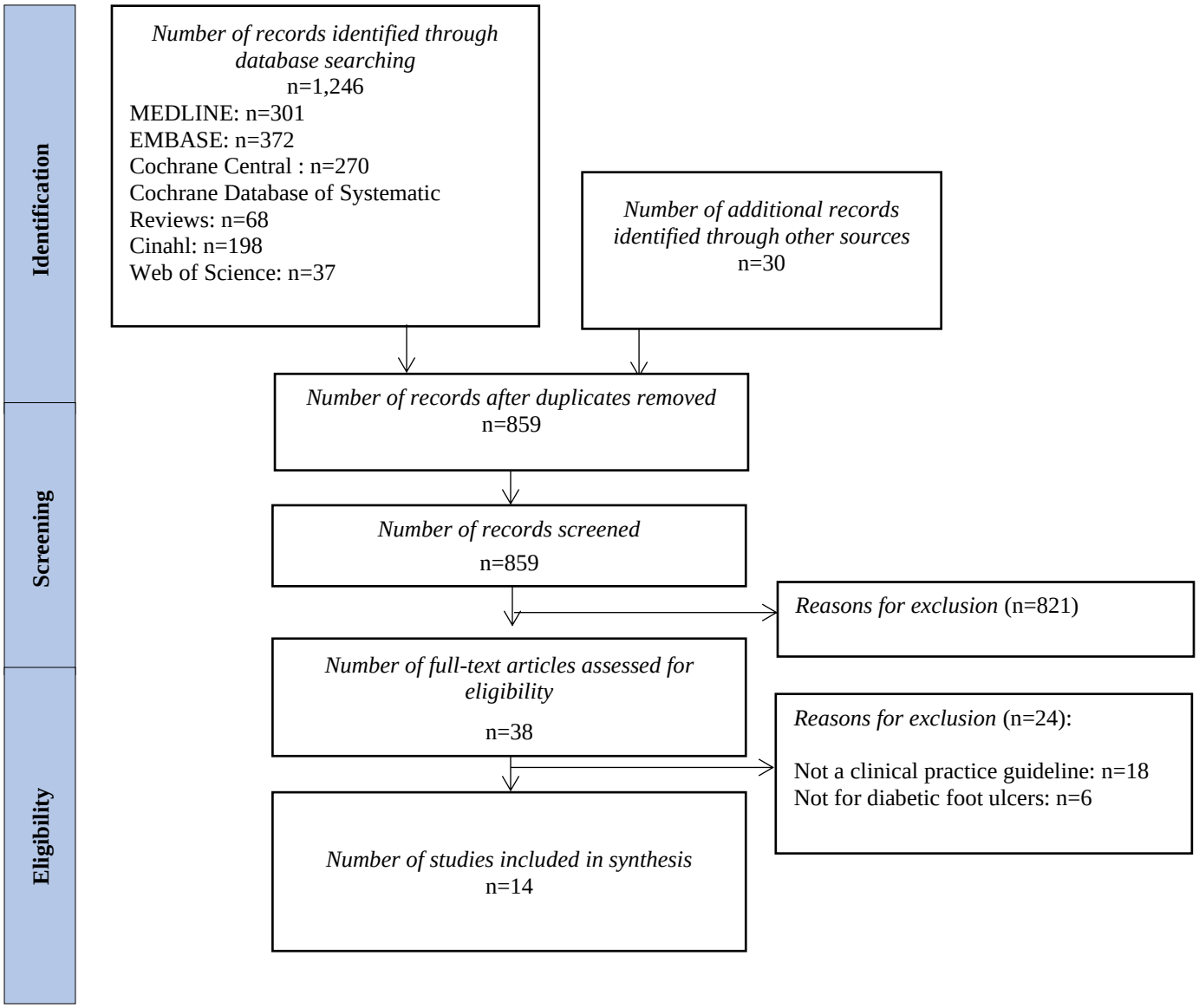
Data from the included guidelines were extracted by one reviewer and verified by another reviewer. Any disagreements were resolved by discussion and consensus. Extracted data included the author of the guidelines, year of publication, country of publication and the summary of recommendations.

5.3 **Results**

A total of 859 unique abstracts were retrieved and screened; 829 from database searching (Figure 5), and an additional 30 records from searching the grey literature. After the initial screen, 38 records proceeded to full text review. During full-text review, 24 were excluded for not being a

clinical practice guideline (n=18) or not for addressing diabetic foot ulcers (n=6); total of 14 guidelines were included in this literature review.

Figure 5: Study Inclusion Flow-chart



A total of 14 guidelines and one consensus statement were identified. Six Canadian guidelines were identified from the following organizations: Alberta Health Services,[52] Wounds Canada,[53] Diabetes Canada,[54] South West Regional Wound Care Program,[55] Registered Nurses' Association of Ontario,[31] and by Saskatchewan Ministry of Health.[56] In addition, two American

guidelines,[41,50] two European guidelines,[57,58] and four international guidelines[5,6,30,59] were identified (Table 10).

Table 10. Guidelines for use of offloading devices for diabetic foot ulcers

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
Alberta Health Services, **Canada**, 2019[52]	Adapted from the New Brunswick Diabetes Foot Care Clinical Pathway by the Diabetes, Obesity & Nutrition Strategic Clinical Network.	NR	Offer: - High risk (hemorrhagic callus, bleeding/draining, dry/black eschar; or pressure related redness over structural deformities; signs of ischemia; or one or more pulses not palpable; or inappropriate footwear causing pressure/skin breakdown): consider offloading affected foot - Urgent risk (infection, red/hot/swollen foot, acute charcot foot, acute pain in previously insensate foot, absent pedal pulses with cold, white, painful foot or toes): total offloading/non-weight bearing of foots - The specialty wound care team can assess plantar pressures and recommend the best offloading approach	- All high risk patients should be referred to High Risk Foot Team or a local specialist with an appointment to be seen within 1-2 weeks, with follow up every 1-4 weeks - Urgent risk DFU may require hospital admission and close medical monitoring
Wounds Canada, **Canada**, 2019[53]	This guideline is an update of the 2017 guideline. It is built on the work of previous author teams and incorporates the latest research and expert opinion. Recommendations are supported by RNAO's level of evidence guideline development panel. Guidelines	Canadian Association of Wound Care (Wounds Canada)	Offer: - Offloading options for the prevention and treatment of forefoot ulcers can be selected according to the risk and severity of complication status and patient acceptability - First line of treatment: devices that cross the ankle joint such as removable contact casts and TCC, irremovable devices are a better option than removable devices, patients must have adequate balance to use these devices - Second line of treatment: devices that do not cross the ankle joint, such as surgical shoes	- Based on identified risk factors, wound and environmental assessments, collaborative goals need to be set with patient, family, and/or caregiver. This care team needs to be engaged throughout the care plan to ensure consistent implementation - Plan of care should include: identifying and implementing an evidence-informed plan to correct the causes or co-factors

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	included in the document to form best practice recommendations include: 2012 IDSA, 2013 Diabetes Canada, IWGDF, APMA, NICE, Wounds International, RNAO, and a quick reference guide for lower-extremity wounds: venous, arterial and neuropathic.		and customized or custom-made footwear and orthotics - Third line of treatment: shoes and orthotics, which are mainly used for prevention. - The best device is a mechanically supportive device that patient will use inside and outside the house Do not offer: - Use TCC with caution for heel ulcers, contraindicated for infected or ischemic wounds - Removable cast walker contraindicated for those with heel ulcers and poor balance - Half shoe (forefoot) contraindicated for patients with gait instability	that affect skin integrity, patient needs, wound, and environmental and system challenges - Optimize local wound environment through cleansing, debriding, managing bacterial and moisture balance, and appropriate dressings and/or advanced therapy
Diabetes Canada, **Canada**, 2018[54]	An executive committee, steering committee and expert committee with broad expertise and geographic representation were assembled. Expert Committee members evaluated the relevant literature, and guidelines were developed and initially reviewed by the Expert Committee.	The 2018 expert committee members were volunteers and received no remuneration or honoraria for their participation.	Offer: - DFU: Insufficient evidence to recommend any specific dressing type for typical DFUs (Grade C, Level 3), debridement of nonviable tissue (Grade A, Level 1A) and general principles of wound care include the provision of a physiologically moist wound environment, and off-loading the ulcer (Grade D, Consensus) - Plantar DFU: removable and irremovable walker boots and total contact casts are effective in decreasing pressure Do not offer:	- People with diabetes who develop a foot ulcer or show signs of infection even in the absence of pain should be treated promptly by an interprofessional health-care team with expertise in the treatment of foot ulcers to prevent recurrent foot ulcers and amputation (Grade C, Level 3)

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	In the absence of new evidence since the publication of the 2013 Clinical Practice Guidelines, recommendations from the 2013 document were not changed.		- TCC to patients to support healing of noninfected, non ischemic plantar surface neuropathic ulcers without going through careful patient selection and personnel who have specialized training to minimize risk of developing iatrogenic complications	
South West Regional Wound Care program, **Canada**, 2018[55]	Developed in collaboration with the Wound Care Champions, Wound Care Specialists, Enterostomal Nurses, and South West Regional Wound Care Program members from long term care homes, hospitals, and south west contracted community nursing agencies in the South West Local Health Integration Network. This initiative incorporates standards outlined by Health Quality Ontario.	NR	Offer: - Plantar forefoot DFUs without ischemia or uncontrolled infection: non-removable knee-high device with an appropriate foot-device interface (i.e. fiberglass TCC) is recommended - When a non-removable knee-high device is contraindicated or not tolerated, removable knee-high walker with an appropriate foot-device interface, with the expectation of patient adherence (i.e. RCW) is recommended - When a knee-high device is contraindicated or cannot be tolerated, a forefoot offloading shoe, cast shoe, or custom-made temporary shoe (i.e. half shoe) is recommended	- Holistic management of an individual with DFU: Assessment: - Thoroughly review the person's available medical records - Review orders and recommendations from the prescriber of the offloading device Planning: - Discuss expected outcomes like appropriate offloading device that minimizes discomfort and ensures adherence to device (if removable) - Explain procedure and purpose to patient and caregivers - Assess the need for analgesia prior to offloading device removal and wound care treatment Implementation:

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
				- An appropriate fitter for initial application, removal and re-application of the offloading device - Assessment and treatment of the DFU completed by an appropriate monitor prior to application of the device
Registered Nurses' Association of Ontario **Canada**, 2013[31]	The RNAO expert panel members were given a mandate to review the original guideline (March 2005) in light of the new evidence. Where necessary, sections of the guideline have been updated based on new evidence from a systematic review/search strategy process. This current edition (2013) is the culmination of the RNAO expert panel's work in integrating the most current and best evidence to update the guideline recommendations and	Ontario Ministry of Health and Long-Term Care	Offer: - Redistribute pressure applied to foot ulcers by the use of offloading devices (Level 1A evidence) - TCC advantages: highest healing rates, distributes pressure over the entire plantar surface, completely offloads, protects foot from infection, controls edema, maintains adherence. - TCC disadvantages: requires trained technician, cannot assess foot on a daily basis, affects sleeping and bathing, exacerbates postural instability or causes poor balance, cannot use if wound infected, cannot be used in the neuroischemic limb - Removable walker advantages: easily removable allowing wound inspection and treatment, allows more comfortable bathing and sleeping, can be used for infected wounds and superficial ulcers, can be made irremovable. - Removable walker disadvantages: removable nature reduces adherence, no	- Assess affected limbs for elevated foot pressure, structural deformities, ability to exercise, gait abnormality, and ill-fitting footwear and offloading devices - Determine potential of DFU to heal and ensure interventions to optimize healing have been explored - Develop a care plan incorporating goals mutually agreed upon by the client and health-care professional to manage DFU, collaborate with the client/family and interprofessional team to explore other treatment options if healing has not occurred at the expected rate or establish mutually agreed upon goals to improve QOL if factors affecting poor healing have

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	supporting evidence from the first edition.		clinical data to support efficacy compared to TCC. - Suggests orthoses can be provided by chiropodists/podiatrists, occupational therapists, orthotists, pedorthists, and physical therapists Do not offer: - Aggressive debridement and moist interactive healing if healing potential of DFU is not established - TCC: if wound infected, and cannot be used in the neuroischemic limb	been addressed and complete wound closure is unlikely. - Implement a plan of care to mitigate risk factors that can influence wound healing - Provide wound care consisting of debridement, infection control and moisture balance where appropriate
Saskatchwan Ministry of Health, **Canada**, 2008[56]	Clinical practice guidelines were developed from 29 references listed in the appendix. A small working group listed on page 6 of the guideline comprised of podiatrists, diabetes educators, wound care nurses, family physicians, vascular surgeon, home care personnel and the Provincial Diabetes Coordinator of Saskatchewan	Saskatchewan Health	Offer: - Pressure offloading is essential for wound healing to occur, especially if there is loss of protective sensation in the foot. - Offloading options that may be considered and provided by a podiatrist or orthopedic specialist include: accommodative dressings (felt, foam, deflective padding), total contact orthoses (custom walking braces), shoe cut-outs, healing sandal/surgical shoe with molded insole, half shoes or wedge shoes, removable walking braces with rocker bottom soles, foot casts or boots, TCC, patellar tendon bearing braces, assistive devices (crutches, walker, cane etc.) and total non-weight bearing (crutches, bed, wheelchair)	- Optimum wound environment for healing includes: wound cleansing, appropriate wound dressings (moisture retentive dressings, dry dressings), management of wound infection, ulcer management (debridement), pain management, prevention of wound trauma (pressure offloading), diabetes management, nutrition management, adjunctive therapies and traditional therapies

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	Health was convened in November 2005. The previous work pertaining to the management of diabetic foot ulcers undertaken by the Saskatoon and Regina Qu'Appelle Health Regions, and the wound care guidelines developed by the Saskatchewan Health Quality Council, were utilized in this guideline development.			
American Podiatric Medical Association, Society for Vascular Medicine, Society for Vascular Surgery, **United States of America**, 2016[50]	Multidisciplinary committee consisting of vascular surgeons, podiatrists, and physicians with expertise in vascular and internal medicine. Five systematic reviews were conducted addressing the effect of glycemic control on preventing DFU, the evidence supporting different	NR	Offer: - Plantar DFU: TCC or irremovable fixed ankle walking boot (Grade 1B) - DFU requiring frequent dressing changes: RCW (Grade 2C). Suggest against using postoperative shoes or standard or customary footwear for off-loading plantar DFUs (Grade 2C) - High risk patients with healed DFU: (including those with a prior history of DFU, partial foot amputation, or Charcot foot) Specific therapeutic footwear with pressure-relieving insoles to aid in prevention of new or recurrent foot ulcers (Grade 1C)	- Attentive care to the DFU requires frequent inspection with irrigation and debridement, protective dressings, infection and inflammation control and plantar offloading - Preserve a moist, non-infected wound environment that will progress through granulation and epithelialization to full healing in a timely manner

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	off-loading methods, adjunctive therapies, debridement, and tests to predict wound healing. The committee reviewed several relevant guidelines from other organizations and societies (American Diabetes Association and IDSA) and adapted several evidence-based recommendations from these guidelines.		Do not offer: - Prophylactic arterial revascularization to prevent DFU - Routine use of specialized therapeutic footwear in average-risk diabetic patients - Postoperative shoes or standard or customary footwear for off-loading plantar DFUs	
Infectious Diseases Society of America, **United States of America**, 2012[41]	Infectious Diseases Society of America format was followed, a panel selected questions to address and assigned each member to draft a response to at least one question in collaboration with another panel member using literature. Panel chair performed a systematic literature	Infectious Diseases Society of America	Offer: - DFU: use offloading particularly important for plantar wounds, also necessary to relieve pressure caused by dressings, footwear, or ambulation to any surface of the wound (strong recommendation, high-quality evidence). The choice of modality should be based on the wound's location, presence of any associated PAD, the presence and severity of infection, and the physical characteristics of the patient and their psychological and social situation - TCC is the "gold standard" device	- Clinicians unfamiliar with pressure offloading or special dressing techniques consult foot or wound care specialists when these are required - Wound care should include sharp debridement of callus and other wound debris or eschar, moist wound healing

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	search for a weekly literature review for updates.		- Use TCC with caution for patients with severe PAD or active infection, as it precludes viewing the wound	
National Institute for Health and Care Excellence, **United Kingdom,** 2019[58]	Collaboration with Public Health England. Informed by a literature review, and the impact guideline will have on costs. Evidence considered by a committee made-up of practitioners, professionals, care providers, commissioners, those who use services and family members or carers. Guidelines updated regularly.	NR	Offer: - Plantar neuropathic, non-ischemic, uninfected forefoot and midfoot diabetic ulcers: non-removable casting to offload plantar neuropathic, offer an alternative offloading device until casting can be provided Do not offer: - Electrical stimulation therapy, autologous platelet-rich plasma gel, regenerative wound matrices and dalteparin, growth factors (granulocyte colony-stimulating factor, platelet-derived growth factor, epidermal growth factor and transforming growth factor beta), or hyperbaric oxygen therapy.	- When deciding about wound dressings and offloading when treating diabetic foot ulcers, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances - Offer one or more of the following as standard care: offloading, control of foot infection, control of ischemia, wound debridement, wound dressings
Health Service Executive, **Ireland,** 2018[57]	The director of the office of nursing and midwifery services and the National Director of Clinical Strategy and Programmes commissioned this project. It is an update of the Best Practice and Evidence Based	Health Service Executive	Offer: - Patients with DFU: offer 1 or more of the following as standard care: offloading, control of foot infection, control of ischemia, wound debridement, wound dressings (Evidence Grade C). Take into account the clinical assessment of the wound and person's preference for wound dressings and offloading (Evidence Grade C). - Neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection: non-	- It is important that possible adverse effects of interventions, including the use of non-removable and removable knee-high offloading devices, and all surgical offloading procedures. Adverse effects should be discussed with the patient for informed shared-decision making (Evidence Grade C)

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	Guidelines for Wound Management HSE in 2009. A literature review of existing wound management guidelines was carried out. Grading of recommendations originated from existing guidelines or were formulated by members of a multidisciplinary team, including clinicians from across disciplines representing a range of clinical settings and from higher education institutes. Consultation with chairs of each National Clinical Care Programmes and other national stake holders was undertaken		removable knee-high device with an appropriate foot-device interface (Evidence Grade C); offer interim alterative offloading device until casting can be provided (Evidence Grade C) - If non-removable knee-high device is contraindicated or not tolerated, offload with a removable knee-high walker with an appropriate foot device interface (Evidence Grade C) - If knee-high device is contraindicated or not tolerated, offload with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer (Evidence Grade C) - Consider referral for orthopaedic opinion/surgical intervention to heal neuropathic plantar foot ulcer and toe ulcers where significant deformity exists and/or conservative treatment fails (Evidence Grade C) - Neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection: If other forms if biomechanical relief are not available, use felted foam in combination with appropriate footwear (Evidence Grade C) Do not offer: - Agents reported to improve wound healing by altering the biology of the wound,	- Instruct patients to monitor foot skin temperature to prevent a first or recurrent plantar ulcer (Evidence Grade C). - To prevent a recurrent plantar ulcer, prescribe therapeutic footwear with demonstrated plantar pressure relieving effect during walking (i.e.,: 30% relief compared to plantar pressure in standard of care therapeutic footwear) (Evidence Grade C). - Prevent recurrent foot ulcers by providing integrated foot care, include: professional foot treatment, adequate footwear and education. Repeat or reevaluate once every 1 – 3 months as necessary (Evidence Grade C)

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
			including growth factors, bioengineered skin products and gases, in preference to accepted standards of good quality care. - Agents reported to have an impact on wound healing through alteration of the physical environment, including through the use of electricity, magnetism, ultrasound and shockwaves, in preference to accepted standards of good quality care. - Systemic treatments reported to improve wound healing, including drugs and herbal therapies, in preference to accepted standards of good quality care.	
International Working Group on the Diabetic Foot, **International**, 2019[5,59]	A multidisciplinary working group of independent experts (the authors of this guideline) was instated by the IWGDF Editorial Board. The members of the working group devised the clinical questions, which were revised after consultation with external experts from various geographical regions and the IWGDF	Production of the 2019 IWGDF Guidelines was supported by unrestricted grants from: Molnlycke Healthcare, Acelity, ConvaTec, Urgo Medical, Edixomed, Klaveness, Reapplix, Podartis, Aurealis, SoftOx, Woundcare Circle, and Essity.	Offer: - Neuropathic plantar forefoot or midfoot ulcer: TCC or non-removable knee-high walker with an appropriate foot-device interface as the first-choice of offloading treatment (strong recommendation, high quality evidence), choice dependent on resource available, technician skills, patient preference and extent of foot deformity (strong recommendation, moderate quality evidence) - Neuropathic plantar forefoot or midfoot ulcer, when non-removable knee-high offloading device is contraindicated or not tolerated: removable knee-high offloading device with an appropriate foot-device	- Multiple interventions along with local wound management, infection management, revascularization are needed for wound care alongside offloading

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
	Editorial Board. A systematic review of literature of the clinical questions was one, quality of evidence was rated. Recommendations were formulated.		interface as the second-choice (weak recommendation, low quality evidence) - Neuropathic plantar forefoot or midfoot ulcer, when knee-high offloading device is contraindicated or not tolerated: ankle-high offloading device as the third-choice (strong recommendation, low quality evidence) - If none available, consider felted foam in combination with appropriately fitting convention or standard therapeutic footwear as the fourth choice (weak recommendation, low quality evidence) - Surgical offloading interventions can be offered if non-surgical offloading treatment fails (weak recommendation, low quality evidence) - Neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischemia: non-removable knee-high offloading device (weak recommendation, low quality evidence) - Neuropathic plantar forefoot or midfoot ulcer with both mild infection and mild ischemia, or with either moderate infection or moderate ischemia: removable knee-high offloading device (weak recommendation, low quality evidence) - Neuropathic plantar forefoot or midfoot ulcer with both moderate infection and moderate ischemia, or with either severe infection or severe ischemia: primarily	

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
			address the infection and/or ischemia, and consider using removable offloading interventions based on the patient's functioning, ambulatory status and activity level (weak recommendation, low quality evidence) - Neuropathic plantar heel ulcer: knee-high offloading device or other offloading intervention that effectively reduces plantar pressure on the heel and is tolerated by the patient (weak recommendation, low quality evidence) - Non-plantar foot ulcer: removable ankle-high offloading device, footwear modifications, toe spacers, or orthoses, depending on the type and location of the foot ulcer (strong recommendation, low quality evidence) Do not offer: - Do not use conventional or standard therapeutic footwear as offloading treatment for patients with neuropathic plantar forefoot or midfoot ulcers unless none of the above mentioned offloading devices are available	
International Working Group on the Diabetic Foot,	NR	NR	Offer: - Neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection: non-removable knee-high device with an appropriate foot–device interface (strong	- Wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar ulcer. When a foot deformity

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
International, 2016[30]			recommendation, high-quality evidence). When a non-removable knee-high device is contraindicated or not tolerated by the patient, consider offloading with a removable knee-high walker with an appropriate foot–device interface, but only when the patient can be expected to be adherent to wearing the device (weak recommendation, moderate quality evidence). When a knee-high device is contraindicated or cannot be tolerated by the patient, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe, but only when the patient can be expected to be adherent to wearing the shoes (weak recommendation, low quality evidence). - Surgical offloading interventions can be offered when conservative treatment fails. - Consider using felted foam in combination with appropriate footwear to offload and heal a neuropathic foot ulcer without ischemia or uncontrolled infection when other forms of biomechanical relief are not available (weak recommendation, low quality evidence). - Informed shared decision-making with patient: give and discuss considerations to possible adverse effects of offloading devices and all surgical offloading procedures.	or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis (strong recommendation, low quality evidence) - Prevent recurrent plantar foot ulcer in an at-risk patient with diabetes by prescribing therapeutic footwear that has demonstrated plantar pressure-relieving effect during walking and encourage patient to wear footwear (strong recommendation, moderate quality evidence)

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
			Do not offer: - Do not prescribe, and instruct a patient not to use, convention or standard therapeutic shoes to heal a plantar foot ulcer (strong recommendation, low quality evidence)	
Wounds International, **International**, 2013[6]	Document draws on local and international guidelines, along with guidance from an extensive international panel of expert practitioners due to lack of high-quality research.	Educational grant from B. Braun	Offer: - Peripheral neuropathy, unilateral uncomplicated plantar ulcer: TCC is the standard care - Ischemic or neuroischemic ulcers: offloading devices that protect the margins of the foot (scotchcast boots or healing sandals) - TCC and non-removable walkers are the preferred interventions - Forefoot offloading shoes or cast shoes may be used when above ankle devices are contraindicated - If recommended devices are not available, and all that can be offered is cushioning, construct from items from local shops (i.e. kitchen sponges, upholstery foams etc.) Do not offer: - TCC are contraindicated in patients with ischemia because of the risk of inducing future DFUs - TCC for patients with infected DFUs or osteomyelitis (no wound inspection)	- Patients with DFU need to be assessed holistically and intrinsic and extrinsic factors considered, history of the wound, previous DFUs or amputation and any symptoms suggestive of neuropathy or PAD should be considered - Essential components of DFU management are: treating underlying disease processes, ensuring adequate blood supply, local wound care, including infection control, and pressure offloading - Patients with DFU should be advised to limit standing and walking and to rest with the foot elevated

Organization	Evidence Source and Process	Funding Source	Recommendations regarding type of offloading device	Recommendations regarding care provision
			- Conventional or standard therapeutic footwear should not be used	

Abbreviations: DFU: diabetic foot ulcers; HSE: Health Service Executive IWGDF: Internationals Work Group on the Diabetic Foot; NR: not reported; PAD: peripheral arterial disease; QoL: quality of life; RCW: removable cast walker; RNAO: registered nurses' association of Ontario; TCC: total contact casts

5.3.1 *Canadian Guidelines*

Six Canadian guidelines published between 2008 and 2019 were identified.[31,52-56] Broadly, these guidelines recommend treatment of DFUs within multidisciplinary clinics or alongside referrals to allied health professionals.[31,52-56] Consistent across all is a recommendation to use offloading for DFUs, and to not use TCC for patients with infected or ischemic wounds.[31,52-56] Follow up to ensure proper and timely healing along with subsequent foot screening exams after ulcer healing, within the prescribed time frame, is also recommended.[31,52-56]

5.3.1.1 Alberta Health Services

In their 2019 guideline, Alberta Health Services (AHS) recommended diabetic patients should be assessed for their risk of developing a DFU when first diagnosed with diabetes, and once a year thereafter; more frequently if deemed high risk.[52] Foot screens examine and assess the patient's feet to identify the state of skin and nails, deformities, arterial compromise, and neuropathy as well as the state of their shoes, both inside and out.[52] AHS has developed The Diabetes Foot Care Clinical Pathway (DFCCP) to aid with early detection and timely treatment of diabetes related foot problems.[52] The DFCCP resources are intended to support healthcare providers in performing diabetes foot screening exams in order to refer patients to the most appropriate healthcare providers within the recommended time frames.[52] This guideline proposes that early detection of risk factors, with timely appropriate interventions can reduce DFU development and subsequently reduce amputations.

An offloading device is recommended for individuals with DFUs. It is recommended that the best approach will be determined by a specialty wound care team who can assess plantar pressure, although this document does not specify which offloading devices should be offered.[52] AHS recommended that high-risk DFU patients be seen within one to two weeks and followed up within one to four weeks.[52] High-risk patients include: patients with hemorrhagic callus, bleeding/draining, dry/black eschar; or pressure related redness over structural deformities; signs of ischemia; or one or more pulses not palpable; or inappropriate footwear causing pressure/skin breakdown and is recommended to consider offloading the affected foot. Urgent patients may require hospital admission for close medical monitoring.[52] This includes patients with infection, red/hot/swollen foot, acute Charcot foot, acute pain in a previously insensate foot, absent pedal

pulses with cold, white, painful foot or toes. It is recommended they receive total offloading and non-weight bearing of the affected foot.[52]

5.3.1.2 Wounds Canada

Wounds Canada 2019 recommends five domains of care in the prevention and management of DFUs.[53] First, the health care provider should assess and/or reassess the patient, the wound, as well as environmental and system changes, and identify risk or causative factors that impact skin integrity and wound healing.[53] Next, goals should be set for prevention, healing, non-healing and non-healable wounds.[53] Based on those goals, a team of appropriate health care professionals and service providers should be assembled for step three; to ensure organizational and system support, patients and their family and caregivers should be enlisted as part of the team.[53] Next, a plan of care should be established and implemented in step four, including: identifying and implement an evidence informed plan to correct the causes or co-factors that affect skin integrity, patient's needs (physical, emotional and social), wound and environmental/system challenges.[53] Local wound environment should be optimized through cleansing, debriding, managing bacterial and moisture balance and appropriate dressings and/or advanced therapy should be selected.[53] The team established in step three must be engaged to ensure consistent implementation of care plan. The last step would be to evaluate outcomes and determine if the outcomes have met the goals of care.[53] This step should also include reassessing patient, wound, environment and system if goals are partially met or unmet, along with ensuring sustainability to support prevention and reduce risk of recurrence.[53]

Within step four, an offloading option is recommended for the prevention and treatment of forefoot ulcers, and the type of device should be selected in accordance to the risk and severity of complication status and patient acceptability.[53] Factors to consider when offloading the foot include presence of any diseases (neuropathy, PAD, inflammatory disorder), the type of pressure (sheer or vertical, intrinsic or extrinsic), the type of ulcer (presence, location, dressing), physical activity (home lifestyle, occupation, recreational, balance), funding (ability to pay for device, insurance) and patient behavior (ability to adhere to treatment plan, occupation and lifestyle, mental capabilities).[53] First line of treatment are devices that cross the ankle joint, such as RCW and TCC, irremovable devices are a better option than removable devices, and patients must

have adequate balance to use these devices.[53] Second line of treatment are devices that do not cross the ankle joint, such as surgical shoes, customized or custom-made footwear and orthotics.[53] Third line of treatment are shoes and orthotics, which are mainly used for prevention.[53] The best offloading device is one that is a mechanically supportive device that the patient will use inside and outside the house.[53]

5.3.1.3 Diabetes Canada

The 2018 Diabetes Canada guideline states that lower extremity complications are a major cause of morbidity and mortality in people with diabetes.[54] Diabetes can cause nerve damage and poor blood flow or circulation to the legs and feet resulting in a decreased ability to feel a foot injury like a blister or cut; diabetes can also make these injuries more difficult to heal.[54] These unnoticed and untreated foot injuries can become quickly infected and lead to more serious complications.[54]

As such, a good daily foot care routine is recommended.[54] Patients should examine feet and legs daily, care for their nails regularly, apply moisturizing lotion if feet are dry (but not between toes), wear properly fitting footwear and test bath water with hand before stepping in to ensure it is not too hot.[54] Other preventive measures against the risk of amputation include regular foot examination by a health care professional, evaluation of amputation risk, regular callus debridement, patient education, professionally fitted therapeutic footwear to reduce plantar pressure and accommodate foot deformities, and early detection and treatment of DFU.[54]
For patients with DFUs, there is insufficient evidence to recommend any specific dressing type, but wound care should be treated promptly by an interprofessional healthcare team.[54] An interprofessional approach should include foot care like debridement of nonviable tissue, moist wound environment, decrease mechanical pressure with offloading and expertise to prevent recurrent foot ulcers and amputation, as well as measures to improve glycemic control.[54]
This guideline suggests pressure offloading may be achieved with temporary footwear until the ulcer heals and the tissues of the foot stabilizes.[54] RCW, ICW and TCCs are effective at decreasing plantar pressure.[54] Although TCC requires careful patient selection and personnel who have specialized training to minimize the risk of developing iatrogenic complications.[54]
When bony foot deformity prevents the fitting of appropriate footwear or offloading devices,

consultation with a surgeon skilled in foot surgery may be considered to evaluate and treat the deformity.[54] For individuals with acute Charcot foot, treatment should include immobilization of the foot, typically for several months in a TCC or RCW or custom orthosis until consolidation occurs.[54] Surgical stabilization may be indicated for Charcot arthropathy associated with marked instability, deformity or non-healing ulcers.[54]

5.3.1.4 South West Regional Wound Care

South West Regional Wound Care 2018 program encourages a holistic management approach for individuals with DFUs.[55] Due to the complex nature, DFU management requires an integrated team or team member to provide specialized holistic care.[55] A detailed description of each role for service implementation is listed along with the qualifications needed (Table 11).[55] A prescriber must have expertise and familiarity with wound care assessment, gait assessment, biomechanics of the lower limb to assess balance and mechanics, and overall knowledge of offloading devices.[55] A fitter must have offloading device application training.[55] A monitor must be able to undertake debridement and have the knowledge, skill, judgment and authority to do so safely and appropriately, the tools in place to control for adverse events like bleeding, the ability to effectively manage pain associated with the procedure, and the organizational policies in place to support their practice.[55]

Table 11. Role Description for Diabetic Foot Ulcer Service Implementation[55]

Role	**Integrated Team Member Qualifications**
Prescriber	• Chiropodists with wound care training • Podiatrists with wound care training • Occupational therapist (OT) & Physiotherapist (PT) with wound care training • Physiatrists (Physical Medicine and Rehabilitation Physicians) with wound care training • Family physicians with wound care training • Orthopaedic surgeon and vascular surgeon with wound care training • Nurse practitioner (NP) with training in gait assessment and wound care
Fitter	• Chiropodists with wound care training & device application training • Podiatrists with wound care training & device application training • OT & PT with wound care training & device application training • Pedorthists with wound care training & device application training • Physiatrists/Orthopaedic surgeon with wound care training & device application/training

	• Family physicians with wound care training & device application training • Health care professionals with certified enterostomal nurse therapist [CETN(C)]; The International Interprofessional Wound Care Course (IIWCC); Western University's Masters of Clinical Science (Wound Healing) (MCISc); Cardiff University's Masters of Science (Wound Healing and Tissue Repair) with device application training • RN & NP with wound care training & device application training • Cast technician (Ortho Techs) with device application training
Monitor	• Chiropodists with wound care training • Podiatrists with wound care training • OT & PT with wound care training • Pedorthists with wound care training • Physiatrist/Vascular surgeon/Orthopaedic surgeon with wound care training • Cast technician (ortho techs) with wound care training • Family physicians with wound care training • RN & ET & NP with wound care training • Health care professionals with CETN(C) & IWCC; MCISc; MSc

Abbreviations: ET: enterostomal therapy nurse; NP: nurse practitioner; OT: occupational therapist; PT: physiotherapist; RN: registered nurse

The health care provider overseeing the offloading device starts with an assessment including a thorough review of the person's available medical records and reviews of the orders and recommendations from the prescriber of the offloading device.[55] Then a plan is formulated, including a discussion of expected outcomes with the patient and their caregivers along with informed verbal or implied consent and an assessment of the need for analgesia prior to the offloading device removal and wound care treatment.[55] The final step is implementation of the offloading device including assessment and treatment of the DFU by the monitor, followed by the initial application, removal and re-application of the appropriate offloading device by a fitter.[55]

This guideline recommends that patients with plantar forefoot DFUs without ischemia or uncontrolled infection be offloaded with a non-removable knee-high device with an appropriate foot-device interface such as fiberglass TCC.[55] When a non-removable knee-high device is contraindicated, use an RCW with an appropriate foot-device interface with the expectation of patient adherence.[53,55] When a knee-high device is contraindicated, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe.[55]

5.3.1.5 Registered Nurses' Association of Ontario

In the Registered Nurses' Association of Ontario's 2013 guideline, affected limbs should be assessed for elevated foot pressure, structural deformities, ability to exercise, gait abnormality and ill-fitting footwear.[31] The potential for the DFU to heal should be determined and interventions for healing should be optimized.[31] A care plan of the interventions should incorporate goals mutually agreed upon by the client and health-care professional to manage DFUs.[31] If healing has not occurred at the expected rate, collaborate with the client/family and interprofessional team is recommended to explore other treatment options.[31] This care plan should also mitigate risk factors that influence wound healing while addressing quality of life factors. DFU wound care should consist of debridement, infection control, and moisture balance where appropriate.[31] The guidelines indicates to not offer aggressive debridement and moist interactive healing if the healing potential of the DFU is not established.[31]

As part of the care plan outlined in the guideline, offloading device should be utilized as pressure alleviation is integral to prevention and formation of calluses and to promote ulcer wound healing.[31] A health-care professional skilled in the fabrication and modification of offloading devices, such as chiropodist or podiatrist should be consulted.[31] The advantages and disadvantages of each offloading device is listed for selection considerations.[31] In brief, TCC advantages include: highest healing rates, ability to distribute pressure over the entire plantar surface, completely offloads, protects foot from infection, controls edema and maintains adherence.[31] TCC disadvantages include: requires trained technician, cannot assess foot on a daily basis, affects sleeping and bathing, exacerbates postural instability or causes poor balance, cannot use if wound infected, cannot be used in the neuro-ischemic limb.[31] RCW advantages include: easily removable allowing wound inspection and treatment, allows for more comfortable bathing and sleeping, can be used for infected wounds and superficial ulcers, can be made irremovable.[31] RCW disadvantages include: removable nature reduces adherence and no clinical data to support efficacy compared to TCC.[31] Orthoses to prevent recurrence can also be provided by chiropodists/podiatrists, occupational therapists, orthotists, pedorthists, and physical therapists.[31] Surgery may be considered if offloading devices are ineffective or not a viable option.[31]

5.3.1.6 Saskatchewan Ministry of Health

The 2008 Saskatchewan Ministry of Health guideline recommends a proactive approach for preventing diabetic foot complications, involving the patient, family/care givers and an interdisciplinary team of health care providers.[56] Optimal diabetes management, daily foot care and education for patients and family/care givers along with screening and risk assessment by trained care providers are all critical aspects for prevention of DFUs.[56] Patients with DFUs require an optimum wound environment for healing.[56] This requires an interdisciplinary approach and a wound treatment team that may include some or any of the following disciplines: family physicians, diabetologists, nurses, dietitians, vascular surgeons, podiatrists, wound resource nurse, diabetes educators, and orthotists.[56] The team would have a care plan that includes: wound cleansing, appropriate wound dressings (moisture retentive dressings, dry dressings), management of wound infection, ulcer management (debridement), pain management, prevention of wound trauma (pressure offloading), diabetes management, nutrition management, adjunctive therapies (electrical stimulation, hyperbaric oxygen, negative pressure wound therapy) and traditional therapies (traditional therapies used by various cultures).[56] For the prevention of wound trauma, a pressure offloading for all wounds options may be considered and provided by a podiatrist or orthopedic specialist.[56] Options include accommodative dressings (felt, foam, deflective padding), total contact orthoses (custom walking braces), shoe cut-outs, healing sandal/surgical shoe with molded insole, half shoes or wedge shoes, removable walking braces with rocker bottom soles, foot casts or boots, TCC, patellar tendon bearing braces, assistive devices (crutches, walker, cane etc.) and total non-weight bearing (crutches, bed, wheelchair).[56]

5.3.2 *American Guidelines*

Two American guidelines were identified, published in 2012 and 2016.[41,50] For patients with DFUs, attentive wound care is recommended and the priority focus of both guidelines.[41,50] Wound care should include wound debridement, moisture control, infection and inflammation control, protective dressings and plantar offloading.[41,50] Both broadly recommended TCC as the standard care device but note that it should not be used if patients require frequent dressing changes due to severe PAD or active infections.[41,50]

5.3.2.1 American Podiatric Medical Association, Society for Vascular Medicine and Society for Vascular Surgery

American Podiatric Medical Association, Society for Vascular Medicine and Society for Vascular Surgery in 2016 recommends attentive care to the wound.[41] This includes frequent inspection with irrigation and debridement, protective dressings, infection and inflammation control and plantar offloading.[41] This moist, non-infected wound environment will allow for wound progress through granulation and epithelialization to full healing in a timely manner. For plantar DFU, TCC or irremovable fixed ankle walking boot is recommended.[41] For DFUs requiring frequent dressing changes, use a RCW and suggest against using postoperative shoes or standard or customary footwear to offload.[41] In patients with non-plantar wounds, use of any modality that relieves pressure at the site of the ulcer, such as a surgical sandal or heel relief shoe is recommended.[41] For high risk patients with healed DFU including individuals with a prior history of DFU, partial foot amputation, or Charcot foot, specific therapeutic footwear with pressure-relieving insoles can aid in prevention of new or recurrent foot ulcers.[41] Although numerous offloading modalities are available with each having its advantages for any given patient, almost any offloading modality is superior to no offloading for the management of DFUs.[41] They also recommend against: prophylactic arterial revascularization to prevent DFU; routine use of specialized therapeutic footwear in average-risk diabetic patients, and postoperative shoes or standard or customary footwear for offloading plantar DFUs.[41]

5.3.2.2 Infectious Diseases Society of America

The Infectious Diseases Society of America 2012 guideline suggests deploying a multidisciplinary team to reduce the likelihood and extent of lower extremity amputations in patients with DFUs.[50] Wound care should include sharp debridement of callus and other wound debris or eschar, moist wound healing, and pressure or weight displacement off the affected area of the foot (offloading).[50] The team should choose an offloading modality based on the wound's location, presence of infection or PAD, physical characteristics of the patient and their psychological or social situation, and decision should be made with consultation from foot or wound care specialists.[50]

Total contact cast is the standard device recommended with its main advantage being that it is irremovable, however, it should be used with caution in patients with severe PAD or active infection, as it precludes viewing the wound.[50] Although there are many types of removable offloading devices from which to choose, patient adherence is a concern.[50] If a diabetic foot wound fails to heal despite wound care, the clinician should initiate a reevaluation of management.[50] This should include ensuring that perfusion of the limb is adequate and that any infection has been adequately addressed.[50] Certain adjunctive treatment like hyperbaric oxygen therapy, platelet-derived growth factors, bioengineered skin equivalents, granulocyte colony-stimulating factor and topical negative pressure can be utilized to promote wound healing.[50] However none of these measures have been shown to improve resolution of infection. Moreover, they are expensive, not universally available and may require consultation with experts.[50]

5.3.3 *European Guidelines*

Two European guidelines were identified, published in 2018 and 2019. Broadly, both recommend use of an offloading device to minimize trauma to the ulcer site.[57,58]

5.3.3.1 National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence published a 2019 updated guideline which recommended an initial clinical assessment of the wound and document the size, depth, position and severity of the ulcer using SINBAD or the University of Texas classification system and to not use the Wagner classification system.[58] For treatment, offer one or more of the following as standard care: control of foot infection and/or ischemia, wound debridement, wound dressings and offloading.[58] Wound debridement should only be done by healthcare professionals with relevant training and skills.[58] Negative pressure wound therapy should be considered after surgical debridement on the advice of multidisciplinary foot care services.[58] For offloading, offer non-removable knee-high casting like TCC for plantar, non-ischemic, uninfected forefoot and midfoot ulcers, and offer an alternative device until casting can be provided.[57,58]

All wound dressings and offloading device treatment decisions should take into account the clinical assessment of the wound and person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances.[58] Consider dermal or skin

substitutes as an adjunct to standard care when treating DFUs, only when healing has not progressed and on the advice of multidisciplinary foot care services.[58] Follow-up care should include professional foot treatment, education and prescribing therapeutic footwear with demonstrated plantar pressure relieving effect during walking to prevent a recurrent plantar ulcer.[58] Follow-up frequency and monitoring should be set out in the person's individualized treatment plan and take into account the overall health of the diabetic patient, how healing has progressed and any deterioration.[58] Guideline indicated that the following should not be offered: electrical stimulation therapy, autologous autologous platelet-rich plasma gel, regenerative wound matrices and Dalteparin, growth factors (granulocyte colony-stimulating factor [G-CSF], platelet-derived growth factor [PDGF], epidermal growth factor [EGF] and transforming growth factor beta [TGF-β]), or hyperbaric oxygen therapy.[58]

5.3.3.2 Health Service Executive

The 2018 HSE guideline recommends offloading with a non-removable knee-high device with an appropriate foot-device interface, to heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection. This guideline suggests offering an alternative offloading device until casting can be provided. If the non-removable knee-high device is contraindicated or not tolerated, offload with a removable knee-high walker with an appropriate foot device interface. If that device is contraindicated or not tolerated, offload with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe.[57] If other forms of biomechanical relief are not available, consider using felted foam in combination with appropriate footwear. There is no evidence to indicate the superiority of using a non-removable versus removable knee-high device, as long as an appropriate foot device interface is maintained.

Patients may prefer not to use a non-removable device due to mobility limitations, and wound care and inspections can take place any time with a removable device. If there is severe infection or ischemic foot ulcers present, it should be resolved before applying an offloading device. All patients wearing a device should be given education and support related to the benefits of wearing the device and risks of non-adherence. To prevent recurrent plantar ulcers, prescribe therapeutic footwear with demonstrated plantar pressure relieving effect during walking along with integrate foot care and education. Guideline also indicated that the following should not be

offered: agents and systemic treatments reported to improve wound healing by altering the biology of the wound or physical environment.[57]

5.3.4 *International Guidelines*

Four international guidelines were identified, published between 2013-2019. All four international guidelines recommend a non-removable knee-high device with an appropriate foot-device interface like the TCC for neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection.[5,6,30,59] Conventional or standard therapeutic footwear should not be used to treat the ulcer, only once healed to prevent recurrent plantar ulcers for at-risk diabetic patients.[6,30]

5.3.4.1 International Working Group on the Diabetic Foot

The International Working Group on the Diabetic Foot 2016 guideline[30] and 2019 guideline along with brief update[5,59] also suggests surgical offloading interventions can be offered when conservative treatment fails.

IWGDF's guideline on offloading foot ulcers in persons with diabetes was published in 2019 along with a brief update.[5,59] The update outlines clearly the first, second, third and fourth choice of offloading treatment to heal a neuropathic plantar forefoot or mid-foot ulcer.[59] TCC or non-removable knee-high walker with an appropriate foot-device interface as the first-choice of offloading treatment.[59] Second choice of treatment is a removable knee-high offloading device with an appropriate foot-device interface.[59] Third choice of offloading treatment is a removable ankle-high offloading device.[59] The fourth choice is felted foam in combination with appropriately fitting conventional or standard therapeutic footwear as treatment if none of the above choices are available.[59] All removable devices require encouragement with patient to wear the device at all times.[59]

Other 2019 updates addresses treatment options for ulcers that are complicated by infection or ischemia.[59] For patients with a neuropathic plantar forefoot or midfoot ulcer with either mild infection or mild ischemia, consider using a non-removable knee-high offloading device.[59] For patients with a neuropathic plantar forefoot or midfoot ulcer with both mild infection and

ischemia or with either moderate infection or ischemia, consider using removable knee-high offloading device.[59] For patients with a neuropathic plantar forefoot or midfoot ulcer with both moderate infection and ischemia or with either severe infection or ischemia, primarily address the infection and/or ischemia and consider using a removable offloading intervention based on the patient's functioning, ambulatory status, and activity level.[59] For patients with a neuropathic plantar heel, offload with any knee-high offloading device tolerated by patient.[59] For patient with a nonplantar foot ulcer, use a removable ankle-high offloading device, footwear modifications, toe spacers, or orthoses, depending on the type and location of the foot ulcer.[59] If non-surgical offloading treatment fails, consider using ATL, metatarsal head resections, or joint arthroplasty for a neuropathic plantar metatarsal head ulcer.[5] Consider using a digital flexor tenotomy for a neuropathic plantar digital ulcer.[5]

The 2016 guideline on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes described offloading device recommendations makes the same recommendations as above.[30] Surgical offloading interventions can also be offered when conservative treatment fails. It also recommends not prescribing, and instructing a patient to use convention or standard therapeutic shoes to heal a DFU.[30] This guideline also outlines the importance of informed shared decision-making with the patient, to give and discuss considerations to possible adverse effects of offloading devices and all surgical offloading procedures.[30] Recommendations regarding care provision and prevention of recurrent ulcers are made in the form of prescribing therapeutic shoes, custom-made insoles, or toe orthosis.[30]

5.3.4.2 Wounds International

Wounds International 2013 guideline indicates essential components of DFU management alongside offloading include treating underlying disease processes, ensuring adequate blood supply, and local wound care, including infection control.[6] Patients with DFU needs to be assessed holistically and intrinsic and extrinsic factors must be considered, along with history of the wound, previous DFUs or amputation and symptoms of neuropathy or PAD during treatment.[6] The 2013 guideline also advised DFU patients to limit standing and walking and to rest with the foot elevated.[6] For patients with peripheral neuropathy and a unilateral uncomplicated plantar ulcer, offload with TCC.[6] For patients with ischemic or neuroischemic

ulcers, offload with a device that protects the margins of the foot such as scotchcast boots or healing sandals.[6] TCC and ICW are the preferred interventions, but forefoot offloading shoes or cast shoes may be used when above ankle devices are contraindicated.[6] If the above recommended devices are not available, offer cushioning constructed from items from local shops like kitchen sponges, upholstery foams etc.[6] Guidelines recommend not offering TCC to patients with ischemia do to risk of inducing future DFUs, and to patients with infected DFUs or osteomyelitis as it does not allow for wound inspection.[6] Conventional or standard therapeutic footwear should not be used.[6]

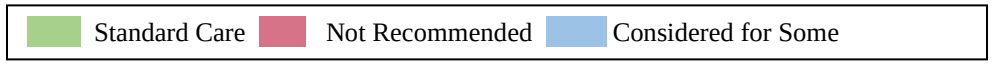
5.3.5 *Comparison of Offloading Recommendations by Guidelines*

All guidelines recommended the use of an offloading device to minimize trauma to the active ulcer site (Table 12). A non-removable knee high offloading device was most frequently recommended, forced adherence may lead to better wound closure. For example, TCC or ICW were recommended as the standard or care in eleven of fourteen guidelines.[5,6,30,31,41,50,53-55,57,58] The exception to this is for those with ischemic or infected wounds, or for those the irremovable offloading device is contraindicated in; six guidelines recommended RCW for patients where TCC and ICW are contraindicated.[5,6,30,53,55,57] Conventional or standard therapeutic footwear should not be used to treat the ulcer, only once healed to prevent recurrent plantar ulcers for at-risk diabetic patients.[5,54,59] However, offer felted foam in combination with appropriately fitting conventional or standard therapeutic footwear as offloading treatment if none of the above choices are available or affordable.[5,6,30,57,59]

Table 12. Guideline Recommendation Summary

	Organization	Offloading device; unspecified	TCC	RCW	ICW	Felted foam with appropriate footwear	Standard footwear	Surgical
Canada	AHS(2019)[52]							
	Wounds Canada (2019)[53]							
	Diabetes Canada (2018)[54]							
	South West Regional Wound Care program (2018)[55]							
	RNAO (2013)[31]							
	Saskatchewan Ministry of Health (2008)[56]							
Other	American Podiatric Medical Association Society for Vascular Medicine, Society for Vascular Surgery (2016)[50]							
	Infectious Diseases Society of America (2012) [41]							
	NICE (2019)[58]							
	HSE (2017)[57]							
	IWGDF (2019)[5,59]							
	IWGDF (2016)[30]							
	Wounds International(2013)[6]							

Abbreviations: AHS: Alberta Health Services; IWGDF: International Working Group on the Diabetic Foot; NICE: The National Institute for Health and Care Excellence; RNAO: Registered Nurses Association of Ontario



5.4 Conclusion

Broadly, guidelines recommended the use of an offloading device to minimize trauma to the active ulcer site. A knee high offloading device was most frequently recommended, with many noting that due to forced adherence, non-removable devices may lead to better wound closure. For example, TCC or ICW were recommended as the standard or care in eleven of fourteen guidelines.[5,6,30,31,41,50,53-55,57,58] The exception to this is for those with ischemic or infected wounds, for which an irremovable offloading device is contraindicated; six guidelines recommended RCW for patients where TCC and ICW are contraindicated.[5,6,30,53,55,57]

It is important to note that although many guidelines recommend types of offloading devices based on effectiveness, many also acknowledge that these decisions must be rooted in patient-centeredness; considering how each might impact patient lifestyle and occupation, which is affordable and accessible, how each may influence a patients ability to perform daily tasks, and taking into consideration a patient's support system. Guidelines describe how offloading device choices and collaborative goals need to be set with patient, family, and/or caregivers.[6,30,31,53,57,58] Some of the included guidelines provided focused recommendations on only DFU offloading, while others provided broader recommendations, for example, wound care provision, preventative care, and maintenance after a healed DFU. Four guidelines indicated that offloading treatment should be offered alongside wound care, including but not limited to wound debridement, infection control and moisture balance, when appropriate.[6,31,57,58]

Guidelines describe the complex nature of DFUs. Given this, there is a requirement to holistically meet patient needs, including physical, emotional and social, while considering environmental or system-related challenges. Also described is the need for patient and caregiver education, and diabetes management alongside wound treatment. As a result, many note that the needs of a patient with a DFU are best met by a multidisciplinary team, including for example, family physicians, diabetologists, nurses, dietitians, vascular surgeons, podiatrists, wound resource nurses, diabetes educators, and orthotists.

6 Systematic Review of Health Technology Assessments on Offloading Devices

Summary

- One HTA and one evidence review of offloading devices for the treatment of DFU were included.
- An HTA from HQO included a review of clinical effectiveness, review of economic evaluations, primary economic evaluation, budget impact analysis, and patient interviews.
- An evidence review conducted by CADTH included reviews of clinical effectiveness and economic evaluations.
- Identified HTAs and evidence reviews agree that TCC or ICW were likely to be the most clinically effective and cost-effective option.
- Identified records highlight a knowledge gap that would benefit from the conduct of a high-quality HTA.

6.1 Purpose

To synthesize health technology assessments and other evidence synthesis products on offloading devices for the treatment of diabetic foot ulcers, including TCC, RCW, and ICW.

6.2 Methods

6.2.1 *Search Strategy*

Two methodologies were employed to ensure all relevant literature was captured: a systematic review of databases, and a grey literature review.

The systematic database search was completed by searching Medline, Embase, Cochrane Central Register of Controlled Trials, Cochrane database of systematic reviews, CINAHL, and Web of Science from inception until May 4th, 2020. Terms aimed to capture the technologies of interest, such as “total contact cast,” “walkers,” “casts,” “aircast,” or “boot” were combined with the Boolean Operator “or.” These searches were combined with terms to indicate the condition of interest, such as “wound healing” or “ulcer.” Terms were searched as text words in titles and abstracts or as subject headings (e.g. MeSH). This search included terms used to narrow the literature to Health Technology Assessments such as “Technology Assessment.” The search

strategy was developed by a research librarian, and PRESS reviewed by another research librarian.[51] The full search strategy is reported in Appendix B – Search Strategy.

The database search was supplemented by a grey literature search guided by CADTH "Grey Matters" document.[60] Grey literature and the websites of known HTA organizations were searched using terms including "offloading," "ulcer," "diabetes," "total contact cast," and "cast walker." Grey literature was searched independently in duplicate.

6.2.2 *Study Selection*

Abstracts identified through database or grey literature searching were screened in duplicate; all abstracts included at this stage by either reviewer proceeded to full-text review. Full-text records were screened in duplicate. Any discrepancies between reviewers' inclusions were resolved through discussion between reviewers. Records were excluded if they did not meet the inclusion criteria (Table 13) or if the study was not available in English or French. Peer reviewed publications identified with searches were considered separately in the systematic review of clinical effectiveness. Only HTAs and evidence reviews that contained most sections of a typical HTA were considered in this chapter.

Table 13. Inclusion and Exclusion Criteria for HTA Review

Inclusion Criteria	**Exclusion Criteria**
• HTA or evidence review on TCC, RCW, or ICW for the treatment of DFUs • English or French Language only	• Not an HTA or evidence review • Not TCC, RCW, or ICW for the treatment of DFUs • If an evidence review, no data extraction from included studies • Not available in English or French

Abbreviations: DFU: diabetic foot ulcer; HTA: health technology assessment; ICW: irremovable cast walker; RCW: removable cast walker

6.2.3 *Data Extraction*

Data from the included HTAs were extracted in duplicate. The following data were extracted from all documents included: study characteristics (author/date, country, study objectives); methods and findings on clinical effectiveness, cost-effectiveness, patient experience; and

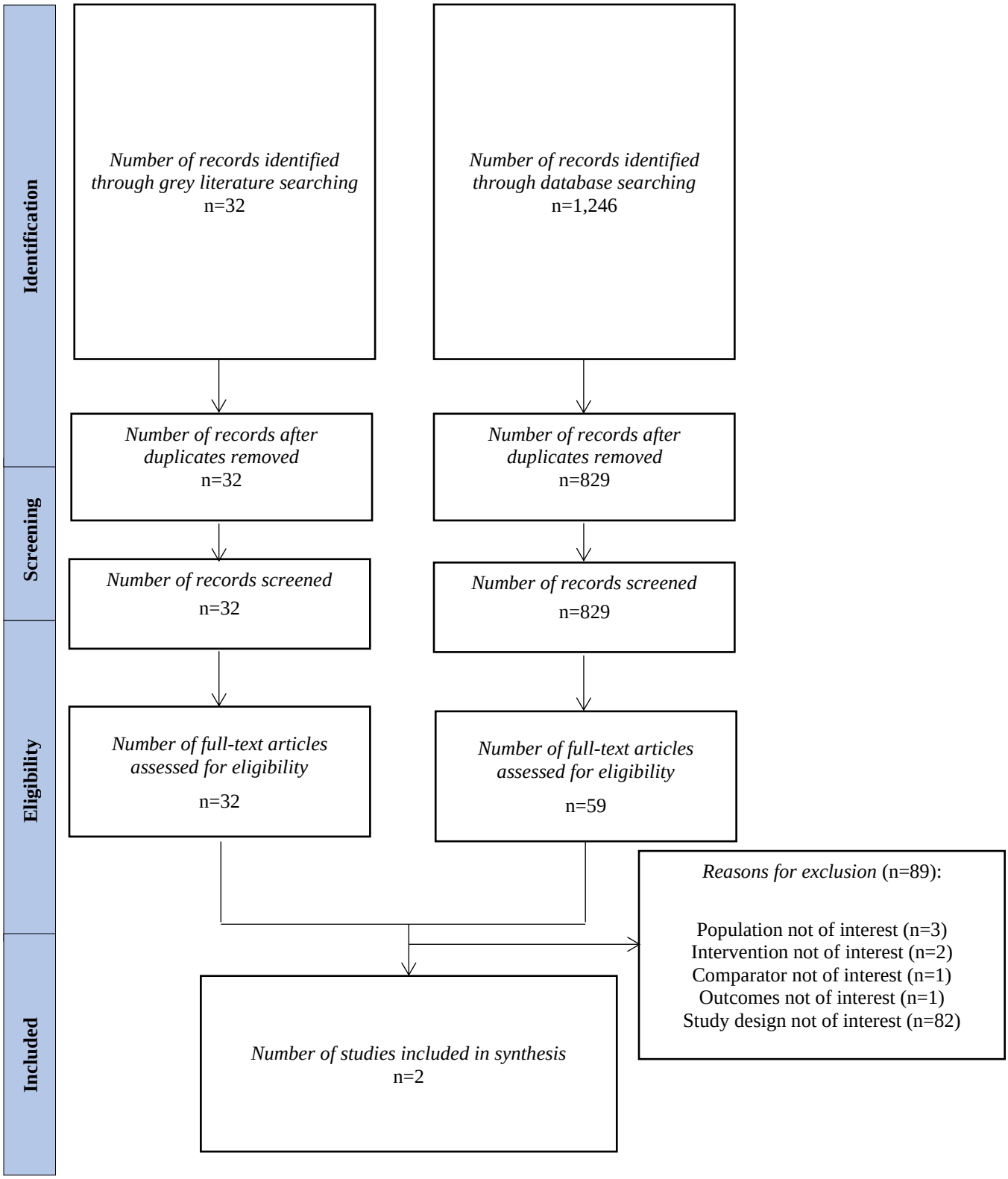
conclusions or recommendations. Discrepancies between reviewers during data extraction were resolved through discussion.

When possible, each component of included records were assessed with relevant quality assessment tools to understand the methodological quality and rigour. This quality assessment was completed independently in duplicate. Following best practice guidelines, systematic reviews or rapid reviews were assessed using the AMSTAR2 tool,[61] economic evaluations were assessed using the Joanna Briggs Checklist for Economic Evaluations,[62] and qualitative research was assessed using the Critical Appraisal Skills Programme Qualitative Checklist.[63]

6.3 Results

Database searches identified 829 unique citations, and grey literature searching identified 32 additional citations (Table 8). For these, 59 full texts from database searching and 32 full texts from grey literature searching (91 full texts in total) were assessed. After full-text review, 90 records were excluded, with the most common reason for exclusion being study design not of interest (n=82). One HTA and one evidence summary met inclusion criteria and formed the final dataset.

Figure 6. Study Inclusion Flow-chart



Characteristics of the final dataset are included in Table 14. The health technology assessment, conducted by HQO, included systematic reviews of clinical effectiveness, cost-effectiveness, *de novo* economic evaluation, budget impact analysis, and semi-structured interviews with patients.[45] The evidence summary, conducted by CADTH, included systematic reviews of clinical and cost-effectiveness.[64] In this evidence summary, which explicitly also included prevention of DFUs, the conducted systematic reviews preferentially included systematic reviews where available, and additional randomized controlled trials or economic evaluations that were not already captured in the preferentially included systematic reviews.[64] Neither of the included records explicitly assessed clinician perspectives.

Table 14. Research objectives and methods.

	HQO (2017) HTA[45]	CADTH (2014) Evidence Summary
Research Questions and Objective(s)	1. What are the clinical benefits and harms of TCC, RCW, and ICW compared with other offloading devices (including each other) and non-offloading treatments in patients with diabetic neuropathic foot ulcers? 2. What is the cost-effectiveness of fiberglass TCC, RCW, and ICW for patients with noninfected diabetic neuropathic foot ulcers? 3. What is the cost-effectiveness and cost-utility of fiberglass TCC, RCW, and ICW in treating patients with noninfected diabetic neuropathic foot ulcers in the context of the Ontario Ministry of Health and Long-Term Care? 4. What is the budget impact of implementing fiberglass TCC, RCW, and ICW over the next 5 years from the perspective of the Ontario Ministry of Health and Long-Term Care? 5. To explore the underlying values, needs, impacts, and preferences of those who have lived experience with the treatment of diabetic foot ulcers. The treatment focus was TCC, RCW, and ICW.	1. What is the clinical effectiveness of removable orthoses for the prevention or treatment of diabetic foot ulcers? 2. What is the clinical effectiveness of TCC for the prevention or treatment of diabetic foot ulcers? 3. What is the comparative clinical effectiveness of removable orthoses versus TCC for diabetic foot ulcers? 4. What is the cost-effectiveness of removable orthoses versus TCC for the prevention or treatment of diabetic foot ulcers?
Clinical Effectiveness	Systematic Review	Systematic Review
Cost-effectiveness	Systematic Review *De novo* Economic Evaluation Budget Impact Analysis	Systematic Review
Patient Perspectives	Semi-structured Interviews	-
Clinician Perspectives	-	-

Abbreviations: CADTH: Canadian Agency for Drugs and Technologies in Health; HQO: Health Quality Ontario; HTA: health technology assessment; ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

6.3.1 *HQO Health Technology Assessment*

The HTA identified was conducted by HQO, and assessed fiberglass TCC, RCW, and ICWs for treatment of DFUs.[45] This HTA included systematic reviews of clinical and cost-effectiveness, a primary economic evaluation and budget impact analysis, and patient interviews.

6.3.1.1 Clinical Effectiveness Systematic Review

In the clinical effectiveness review, inclusion criteria specified that TCC were made with fiberglass, and 13 randomized controlled trials were included.[45] Although impossible to blind patients to treatment, lack of blinding was not considered to confer high risk of bias for outcomes of ulcer healing and time to ulcer healing.[45] Overall, risk of bias was deemed to be low in included studies, especially for ulcer healing.[45] In meta-analysis, TCC and ICWs healed more ulcers than RCW.[45] Treatment characteristics, such as expertise required for application or convenience, and patient characteristics such as leg length and foot deformity, suggest a one-size-fits-all approach to treatment is unlikely to be successful.[45]

Based on the AMSTAR2 tool,[61] which suggests risk of bias in systematic reviews but does not provide an overall score, limitations to this clinical effectiveness systematic review included: lack of protocol, no justification of study designs included, publication restrictions in search strategy not justified, study selection not performed in duplicate, data extraction not performed in duplicate, excluded studies not justified, reasons for combining data in meta-analysis not provided, impact of risk of bias on meta-analytic results not assessed, risk of bias not accounted for in interpretation, heterogeneity not explored, publication not explored, and source of funding or conflicts of interest not reported. Strengths of this systematic review included: clear research question, included studies described in adequate detail, use of Cochrane Risk of Bias tool for quality assessment, and sources of funding for included studies reported.

6.3.1.2 Cost Effectiveness Systematic Review

The systematic review of cost-effectiveness identified one economic evaluation, using decision-tree models to compare soft-heel casting and orthotic footwear in patients with diabetes, from the perspective of the National Health Service in the United Kingdom.[45] Outcomes related to

preventative and treatment of DFUs were modelled.[45] Data regarding the time horizon was not extracted.[45] This study found net cost savings from using soft-heel casting to treat DFUs.[45]

Although research question and inclusion criteria of the review were clearly described, neither of the interventions in the included study match the review's stated inclusion criteria, which is noted in the HQO HTA.[45] Other major limitations to this systematic review include a lack of protocol, lack of justification of publication restrictions, study selection not performed in duplicate, data extraction not performed in duplicate, excluded studies not provided or justified, failure to describe included studies in adequate detail, source of funding for included studies not reported on, and source of funding or conflicts of interest for study authors not reported. Strengths of this review were a clear research question, risk of bias assessment for included studies, and accounting for risk of bias in results interpretation.

6.3.1.3 Economic Evaluation and Budget Impact Analysis

The primary economic evaluation consisted of a decision-tree model comparing TCC, RCW, ICW, and therapeutic shoes, from the perspective of the Ontario Ministry of Health and Long-Term Care.[45] HQO notes that none of these offloading devices were routinely funded in Ontario.[45] Cost per quality adjusted life year was calculated over a six-month time horizon, and cost per ulcer healed was calculated over a three-month time horizon.[45] Terminal nodes corresponded to health states for healed ulcers, unhealed ulcers, and amputations; patients having unhealed ulcers at the halfway point try a second offloading treatment 50% of the time in the base case analysis.[45] In scenario analysis, this proportion was adjusted to 0% and 100% proceeding for second line treatment.[45] Key assumptions noted by HQO were no recurrence of ulcers, each patient experienced only one ulcer, only patients with a DFU who were treated as outpatients were included.[45]

In the base case analysis, the least expensive option was ICW, with a cost per patient of $877, probability of ulcer healing of 0.73, and 0.266 expected quality adjusted life years (QALYs).[45] Compared to this treatment, RCW and therapeutic shoes were expected to result in fewer ulcers healed and fewer QALYs at greater cost, and were therefore dominated.[45] The incremental cost per additional ulcer healed with TCC was $17,923 and the incremental cost per QALY gained

with TCC was $198,928.[45] Key variables influencing outcomes were time to healing and probability of healing. This analysis concludes that ICWs were approximately as effective as TCC, but associated with reduced costs.[45] Therefore, ICWs should be the preferred option when acceptable to patients and clinicians.[45] In the budget impact analysis, the proportion of patients with access to offloading devices was varied between 25% and 100%.[45] When access to offloading devices was increased, the health care system would expect cost-savings due to fewer amputations.[45]

Limitations of this analysis include a reliance upon expert opinion for costing and limited exploration of uncertainty; generalizability of these findings to the British Columbia context is unclear. Failure to include the current funded standard of care in Ontario as a treatment comparator limits usability of findings, and ability to determine cost-effectiveness of any offloading intervention. Strengths of this analysis included a well-defined question with comprehensive description of alternatives, capturing of relevant costs and outcomes for alternatives, established clinical effectiveness, and incremental analysis of costs and consequences.

6.3.1.4 Patient Interviews

The HQO HTA also included semi-structured interviews with 16 patients with DFUs from across Ontario.[45] This analysis intended to explore the values, needs, impacts, and preferences of those with lived experience with the treatment of DFUs.[45] A modified grounded theory methodology was used to analyze transcripts of interviews, although the methodology is poorly described and not justified.[45] Although this HTA describes purposive sampling intended to recruit patients, caregivers, and families, no caregivers or families participated in interviews.[45] No patients with experience or familiarity with ICW were included.[45]

Based on patient interviews, DFUs were associated with a significant daily burden of care and emotional weight.[45] Possibility of amputation leads patients to seek out effective means of treatment; with the most effective treatment perceived to be TCC, over RCW.[45] However, patients also consider cost, comfort, and convenience in the selection of offloading devices.[45]

One illustrative quote from an interview participant demonstrated that ultimately, patients valued effectiveness of ulcer healing:

> *"I really had to choose. I want my foot to be better, and that's the way it has to be. So if that's the way it is, if walking in this air cast is not going to allow my foot to heal and I have to go back to [TCC], well, I absolutely will do that, but you have to want to be better for sure to have that big cast on.*[45]"

Although the research question and statements of findings were clear, limitations to this analysis include a lack of justification for methods, inadequate consideration of the relationship between researchers and participants, lack of discussion of ethical issues related to research or approval by an ethics committee, and a lack of description of data analysis.

6.3.1.5 Recommendations

HQO concludes that although TCC and cast walkers may be beneficial, evidence Grading of Recommendations Assessment, Development, and Evaluation (GRADE) rating is very low to moderate quality across all comparisons.[45] Treatment discontinuation was identified as occurring relatively often with all treatments evaluated.[45] The primary economic evaluation concludes that ICW and TCC were more effective than therapeutic shoes or RCW.[45] HQO recommends that ICWs should be the preferred option, followed by TCC, and then RCW for patients that were ineligible for or have not had success with ICW or TCC.[45] The budget impact analysis suggests that access to offloading devices would have a cost of $17 to $20 million per year but could result in cost savings for the health care system due to amputations avoided.[45] From patient interviews, it was concluded that TCC was preferred over RCW due to perceived faster healing.[45] HQO concludes that TCC and ICW show better healing than RCW, and were also more cost-effective; if more people used these devices, the health system would likely save money due to fewer amputations.[45]

6.3.2 *CADTH Evidence Synthesis*

One document was identified, which contains some but not all typical components of an HTA. This evidence synthesis was conducted by CADTH, and examined the clinical and cost-effectiveness of total removable orthoses and TCC for the treatment and prevention of DFUs.[64] Three systematic reviews and six randomized controlled trials (RCTs) examining clinical effectiveness were included.[64] The consensus among included studies was that TCC and instant total contact casts (iTCC) (also known as an ICW) were the most effective treatments; however, patient adherence, patient withdrawal, and lack of blinding complicate interpretation of findings.[64] No evidence identified a statistically significant difference in clinical outcomes for TCC versus iTCC.[64] In the case of infections, contralateral foot ulcer, significant arterial insufficiency, and balance problems, TCC is contraindicated.[64]

In CADTH's evidence summary, a single cost-effectiveness analysis from the United Kingdom was identified, examining the use of soft-heel casts or orthotic boots for treatment of DFUs, over a one-year time horizon.[64] In this economic evaluation, conducted from the perspective of the publicly funded healthcare system, cost-savings of 10% were found when using soft-heel casting for DFU prevention.[64] CADTH notes that this economic evaluation is limited by significant assumptions, and over-reliance on a data source of unclear quality.[64]

Based on the AMSTAR2 tool,[61] major limitations to this evidence summary were: lack of protocol, no explanation of inclusion criteria related to study design, search strategy not comprehensive or provided, study selection not performed in duplicate, data extraction methods not specified, excluded studies not justified, and no specification of funding sources or conflicts of interest. Strengths of this review were: clear statement of research question, details of included studies provided, risk of bias assessment, discussion of potential impact of risk of bias, and discussion of heterogeneity or variation between studies.

6.3.2.1 Recommendations

Although complicated by patient adherence, patient withdrawal, and lack of blinding, CADTH concluded that TCC and iTCC were the most clinically effective treatments for DFUs.[64] No evidence of statistically significant differences in clinical outcomes for TCC relative to iTCC

were identified.[64] Three randomized controlled trials found that customized footwear and orthoses provide effective prevention of DFUs for adherent patients.[64] No statistically significant differences in the frequent of adverse events were identified between any of the investigated offloading devices.[64] Although cost-effectiveness evidence was limited, one study found that soft-heel casting may offer cost-savings for DFU treatment and prevention; with the caveat this finding was based on significant assumptions.[64]

6.4 Conclusions

Identified evidence was limited. Although there were differences in research questions or objectives, and the methods used, such as the preferential inclusion of systematic reviews in the evidence summary by CADTH, both studies reach similar conclusions. Additionally, both included records were generated in Canada. The HTA by HQO explicitly included only clinically effectiveness evidence for TCC made with fiberglass; other materials used for TCC were excluded. However, CADTH made no distinction based on materials used for TCC. The evidence review from CADTH also examined *prevention* of DFUs, and found that customized footwear and orthoses were effective interventions.[64]

Both reports identified the same economic evaluation, which found that soft-heel casting may offer cost savings relative to orthotic boots for the prevention and treatment of DFU. HQO conducted a *de novo* economic evaluation, finding that ICWs have similar efficacy to TCC for the treatment of DFUs but were less costly.[45] Both included records suggest that TCC or ICW were most likely to be the most clinically effective and cost-effective offloading treatment (Table 15). Although the two identified records were in agreement, the limited evidence in this space highlights a knowledge gap that would benefit from the conduct of a high-quality HTA that includes clinician perspectives, such as the present HTA.

Table 15. Recommended Offloading Device, by section

	Clinical Effectiveness Systematic Review	Cost-effectiveness Systematic Review	Primary Economic Evaluation	Patient Interviews	**Recommendations**
HQO[45]	TCC and removable or ICW	Soft-heel casting	ICW	TCC	TCC and ICW
CADTH[6][4]	TCC and iTCC	Soft-heel casting	-	-	TCC and ICW; soft-heel casting

Abbreviations: ICW: irremovable cast walker; iTCC: instant total contact cast; RCW: removable cast walker; TCC: total contact cast

7 Jurisdictional Scan of Offloading Device Implementation for Diabetic Foot Ulcers across Canada

Summary

- Offloading devices (TCC, RCW, half shoe) are publicly funded for the treatment of DFU in Ontario. Shoes and insoles are partially funded in Quebec and for prevention after healing in Alberta, funding is on hold in Ontario.
- Ten Canadian offloading providers from Alberta (n=3), Manitoba (n=2), Ontario (n=2), Prince Edward Island (n=1) Saskatchewan (n=1), and Quebec (n=1) were surveyed about offloading treatment for DFU in their clinic/province.
- Across Canada, treatment pathways for patients with DFU varies. Treatment is provided by multidisciplinary care teams or by referrals to allied health professionals
- Most provinces follow the Wounds Canada best practice recommendations and/or the IWGDF clinical practice guidelines.

7.1 Purpose

To understand how offloading devices have been integrated into the treatment of DFUs across Canada.

7.2 Methods

A survey was developed and circulated to Canadian offloading device providers via email. The purpose of the survey was to understand the role of offloading devices in treating DFU in each jurisdiction. Survey questions pertained to the treatment pathway, clinical practice guidelines used, type of offloading devices offered, benefits and drawbacks for those offloading devices and the amount of funding available for these devices. Full survey questions are available in Appendix A – Jurisdictional Scan Survey Questions.

An attempt was made to locate contact information for at least one offloading device provider from each province and territory, with the exception of BC. In-depth interviews were conducted with BC clinicians and a detailed description of current practice in this province can be found in Section 12.

7.3 **Results**

The survey was sent to 65 Canadian offloading device providers. Responses were received from ten providers across six provinces: Alberta (n=3), Manitoba (n=2), Ontario (n=2), Prince Edward Island (n=1) Saskatchewan (n=1), and Quebec (n=1). Respondents had the following occupations: podiatric surgeon (n=2), geriatric physician (n=1), pedorthist (n=1), orthopedic technologist (n=1), infectious disease specialist (n=1), chiropodist and diabetes educator (n=1), family physician and academic researcher (n=1), ER and family physician (n=1), and registered nurse (n=1).

Nearly all survey respondents offered TCC and RCWs within their practice, and most also offered insoles or orthotics (Table 16). Other devices offered included, therapeutic shoes, knee scooters, and crutches. No survey respondents reported offering ICWs. Care providers reported following a variety of clinical practice guidelines, including those from IWGDF, the Pedorthic Association of Canada, Wound Canada, the Southwest regional pathway, RNAO and the Canadian Diabetes Association. Based on responses, public funding for offloading is available in Alberta, Ontario and Quebec, to varying degrees (Figure 7).

Table 16. Summary of Survey Responses from Offloading Device Providers[+]

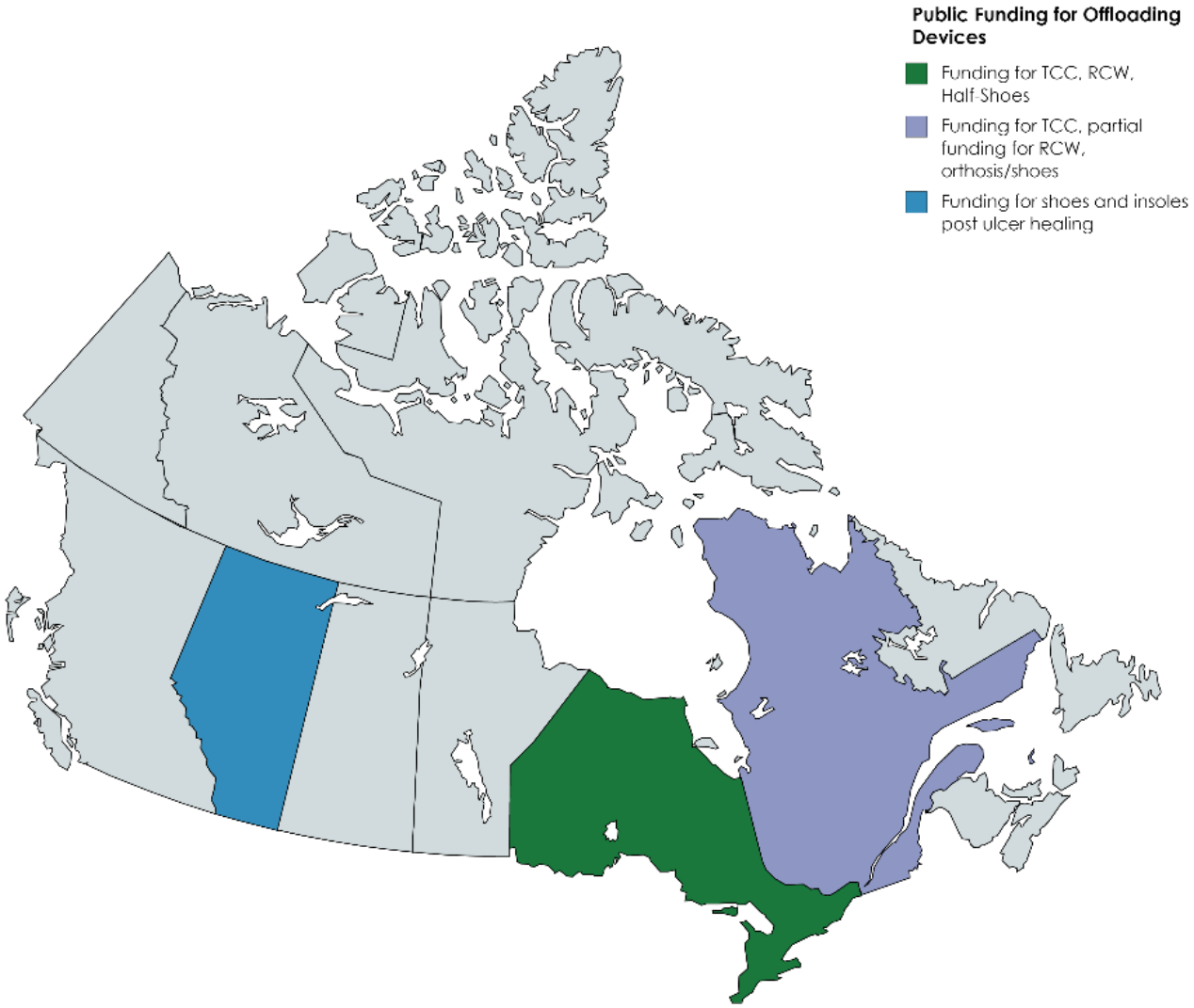
Province of Respondent	Clinical Practice Guidelines Followed by Respondent	Offloading Devices Offered By Respondent(s)	Funding
Alberta (n=3)	• IWGDF	• TCC • Aircast • Darco shoes with PEG assist • Surgical shoes with padding • SBI Motus smart boot • Shoes and insoles	• AADL offers full coverage of shoes and insoles for patients who have healed a wound or an amputation and partial coverage up to 80% based on income for pre-ulceration patients who are high risks for ulceration[65] • Surgical shoes given out to post-op patients • AISH • Private insurance
Saskatchewan (n=1)	• Pedorthic Association of Canada's Clinical Practice Guidelines	• TCC • Custom orthotics • Half shoe	• None[66,67] • NIHB[68] • Private insurance
Manitoba (n=2)	• Wounds Canada	• TCC • RCW • Custom foot orthoses • Custom shoe modification • Custom AFOs	• None[69,70] • TCC in certain hospital's operating budgets • Other devices funded by Manitoba Health for Charcot foot • NIHB[68] • Private insurance
Ontario (n=2)	• IWGDF • Wounds Canada • HQO's quality statements • Southwest Regional pathway	• TCC • RCW • Half shoe • Shoes and orthotics	• Two brands of TCC, RCW and 1 half shoe brand are covered through local health authorities[71,72] • Shoe and orthotics for patients with healed ulcer funding is agreed to but on-hold
Quebec (n=1)	• IWGDF • Wounds Canada • Canadian Diabetes Association	• TCC • RCW • Shoes and orthotics	• TCC coverage unknown • Partial coverage of other offloading devices and shoes and orthotics[73]

Prince Edward Island (n=1)	• RNAO	• TCC • RCW • Half shoes • Knee Scooters • Crutches	• None[71,74]

[+] Table summary based on the few survey responses received and may not be an accurate representation of offloading use across each province

Abbreviations: AADL: Alberta Aids to Daily Living; AFO: ankle foot orthoses; AISH: Assured Income for the Severely Handicapped; HQO: Health Quality Ontario; IWGDF: International Working Group on Diabetic Foot; NIHB: Non-Insured Health Benefits; RCW: removable cast walker; RNAO: Registered Nurses' Association of Ontario; TCC: total contact cast

Figure 7. Public Funding for offloading devices across Canada, based on survey responses[+]



[+] Table summary based on the few survey responses received and may not be an accurate representation of offloading use across each province

7.3.1 *Alberta*

Three Alberta offloading device providers responded to the survey. Two respondents reported following IWGDF guidelines and reported that standard wound care includes wound debridement, minimizing risk of infection and offloading of foot.

Two respondents, who worked in a specialized wound clinic, do not offer TCC. They cited reasons such as the cost of TCC, associated staffing costs, lack of readily available cast technicians, increased risk of infection or worsened ulcers if patient gets cast wet or does a substantial amount of walking, and the inability for patient to be actively involved with their wound care. At their clinic, they offer RCWs like Aircast, Darco shoes with PEG assist, surgical shoes with padding, ProCare shoes and the more costly SBI Motus smart boot for individuals who have insurance. At the other respondent's clinic, they offer all devices, however casting is done by orthopedics.

Two respondents noted that within Alberta, patients may have funding through private insurance, or AISH. Alberta Aids to Daily Living (AADL) also covers the cost of shoes and insoles for patients who have healed a wound or an amputation. Patients who are high risks for ulceration but have never had a DFU can also receive partial coverage for shoes and insoles from AADL up to 80% based on income. A respondent described how RCW and other removable devices like ProCare shoes or crutches are dispensed at hospitals or affiliated clinics, and followed-up with a bill at a later time, although often payment is not received.

It was noted by two respondents that although offloading is essential, it is also necessary to have multidisciplinary limb preservation teams (described as "Toe and Flow Teams") in place. A respondent noted that Alberta is currently the only place in Canada that provides access to podiatric surgeons; noting there has been a 45% reduction in diabetes-related amputation rates as a result.[75]

7.3.2 *Saskatchewan*

One Saskatchewan provider responded to the survey. They described how a primary care provider completes a full assessment of the neuropathic foot ulcer and widely refers the patient

to either publicly-funded allied health professionals or privately funded podiatry clinics to provide offloading devices. They followed provincial resources and the Pedorthic Association of Canada's Clinical Practice Guidelines 2nd edition.

According to the respondent, offloading strategies are dependent on the wound severity, location and other factors. This respondent noted that at their clinic, RCW are not provided, but there are footwear modification options available such as half shoes, forefoot rocker shoes. Prescribed custom orthotics made by qualified providers using true 3D modeling are funded in full or in part by private insurers, as well as by NIHB.

7.3.3 *Manitoba*

Two Manitoba providers responded to the survey. They reported that there is no formal pathway, patients are typically referred to a physician, and assessed in a foot care clinic. These respondents describe following the IWGDF and Wounds Canada guidelines. They described offering wound care followed by an offloading device, TCC, pneumatic and diabetic cast boots (with and without custom foot orthosis), custom ankle/foot orthoses, and shoe modifications.

TCC was reported by both respondents to be the standard care. TCC is not publicly funded but reported by these respondents as covered through hospital operating budgets. According to these providers, cast boots, custom foot orthoses, and custom shoe modifications are funded by Manitoba Health for Charcot foot but not ulcers; and also funded by NIHB.

7.3.4 *Ontario*

Two Ontario offloading device providers responded to the survey. It was noted that the Ontario Ministry of Health is in the midst of developing a clinical diabetic foot pathway. One provider currently follows Wounds Canada's treatment pathway while the other follows a pathway set by the Southwest Region. The southwest region's pathway starts with an annual foot screening, assignment of risk category by following IWGDF's guidelines and subsequent specific recommendations are made based on risk category, patients with highest risk category were to be referred to specialized centers. Treatment is guided by the quality statements from HQO and informed by the Wounds Canada Best Practice Recommendations and IWGDF guidelines.

Both respondents provide all types of offloading devices, including TCC, RCW, and half shoe for forefoot ulcers. All these devices are funded based on their regional working group's decision.

One respondent described devices that treat patients with active pathologies at point of care are funded by government-funded clinics. Prior to the COVID-19 pandemic, Ontario had agreed to fund shoes and orthotics for prevention of recurrence through local health authorities, however this has been put on hold.

7.3.5 *Quebec*

One Quebec care provider responded to the survey. Wounds Canada Best Practice Recommendation, IWGDF and Canadian Diabetes Association guidelines are typically followed. All offloading devices except TCC are offered by this provider, TCC was reported to be only offered in some wound care clinics or specialized clinics in hospitals. They reported that TCC is funded in full after evaluation by a wound care clinic or hospital and other offloading devices and orthosis/shoes are funded partially. This was not verified by other published sources so there remains a lack of clarity about TCC funding.

7.3.6 *Prince Edward Island*

One Prince Edward Island provider responded to the survey. This provider administers treatment in accordance to RNAO's clinical best practice guidelines along with patient education provided by the nurses.

This clinic offers TCC, RCW, therapeutic shoes, knee scooters and sometimes crutches, with TCC and RCW being the most popular. This respondent reported that no public funding is provided for offloading devices.

7.4 **Conclusions**

Across Canada, treatment pathways for patients with DFU vary. Survey respondents from Alberta, Manitoba, Ontario and Quebec follow the Wounds Canada best practice

recommendations and/or the IWGDF clinical practice guidelines. Most respondents offer a variety of offloading devices to their patients, all but two providers among those who responded offer TCC. None of the respondents surveyed actively offer ICW.

Most offloading devices are reported as not being funded within Canada. TCC, although not covered, is reported by certain survey respondents as included in hospital clinic budgets for Alberta, Manitoba, and Quebec. TCC, RCW and a half shoe for forefoot ulcers are reported to be funded by Ontario's local health authority. In addition, a policy decision was made to fund shoes and orthotics for prevention after healing but this has been put on hold due to the COVID-19 pandemic. Shoe and insoles are described by the provider as partially funded in Quebec, and are funded for prevention of recurrence after a healed ulcer or amputation in Alberta through AADL. Alberta providers reported that funding for offloading devices is available through NIHB or AISH for individuals that qualify.

8 Systematic Review of Clinical Effectiveness and Safety of TCC, ICW, RCW, and other Offloading Devices

Summary

- Seventeen studies were identified that explored the clinical effectiveness and safety of offloading devices including TCC, ICW, and RCW, of which eight permitted inclusion in meta-analysis for two outcomes: ulcers healed and time to ulcer healing
- For ulcers healed, there was no statistically significant difference for the risk ratio of TCC compared to ICW (95% CI: 0.93 to1.2), or TCC versus RCW (95% CI 0.99 to 1.36). However at 12 weeks, ICWs were 1.4 times more likely to result in ulcer healing than RCWs (95% CI: 1.0 to 1.97)
- For mean time to healing, there was no statistically significant difference for TCC versus ICW (95% CI: -0.4 to 0.37), TCC versus RCW (95% CI: -2.48 to 0.55), or ICW versus RCW (95% CI: -1.26 to 0.08).

8.1 Purpose

To assess the comparative safety and effectiveness of offloading devices for diabetic foot ulcers including total contact casts, irremovable cast walkers, and removable cast walkers.

8.2 Methods

8.2.1 *Literature Search*

A systematic review of the literature was completed. The literature search was conducted in accordance with the PRISMA guidelines.[76] MEDLINE, EMBASE, Cochrane SR, Cochrane Central, CINAHL, and Web of Science were searched for studies published from inception until May 4th, 2020. Terms aimed to capture the technology of interest, such as "cast," "walker" and "boot" were combined using the Boolean Operator "and," with disease terms, such as "diabetic foot ulcer." These terms were searched as text words in titles and abstracts and as MeSH subject headings when applicable. The search was limited to exclude case reports, animal studies, conference abstracts, editorials, and letters. The search strategy was developed by a research librarian, and PRESS reviewed by another research librarian.[51] The full search strategy is reported in Appendix B. This search was supplemented by hand-searching the reference lists of

systematic literature reviews and recent HTAs, to ensure that all studies meeting the inclusion criteria were captured.

8.2.2 *Literature Selection*

Abstracts identified through database searching were screened in duplicate; all abstracts included at this stage by either reviewer proceeded to full-text review, to ensure all relevant literature was captured. Full-text publications were screened in duplicate. Any discrepancies between reviewers' inclusions were resolved through discussion between reviewers. Publications were included if they met all inclusion criteria, and failed to meet all exclusion criteria outlined in Table 17. Only studies examining at least one of the comparators of interest were included (e.g., total contact cast, irremovable cast walker, or removable cast walker).

Table 17. A priori *Systematic Review Inclusion and Exclusion Criteria*

Inclusion Criteria	Exclusion Criteria

• Adults patients (>18 yrs) with diabetic (type 1 or 2) neuropathic plantar ulcers, infected or uninfected
• Ulcers involving the foot (below the ankle)
• Randomized controlled trial evaluating at least one of the following interventions:
  o fiberglass total contact casting
  o removable cast walker
  o irremovable cast walker
• Report at least one of the following outcomes:
  o Treatment discontinuation
  o Ulcer healing
  o Time to ulcer healing
  o Step-down treatment ('lower level' offloading modalities)
  o Patient adherence to treatment
  o Quality of life and patient satisfaction
	• All other types of diabetes (e.g., gestational, post-pancreatectomy diabetes)
	• Ulcers other than neuropathic plantar ulcers (including ischemic ulcers or venous stasis ulcers)
	• Ulcers involving the ankle or above
	• All non-randomized controlled trial study designs
	• Editorials, case reports, commentaries
	• Studies evaluating solely total contact casting prepared with material other than fiberglass

○ Complications ○ Reoccurrences ○ Amputations • Offloading devices may be used for treatment of current ulcer or prevention of ulceration	

8.2.3 *Data Extraction*

For all included studies, year of publication, country, study design, offloading device, patient characteristics, treatment protocol (e.g., intention to treat, per-protocol), follow-up time, and all outcomes reported were extracted in duplicate using standardized data extraction forms. Discrepancies between reviewers during data extraction were resolved through consensus.

8.2.4 *Quality Assessment*

The quality of each included study was assessed using the Cochrane Handbook Risk of Bias Assessment Tool (version 5.1.0).[77] Each study was assessed using seven criteria broadly covering the areas of randomization, allocation concealment, blinding of participants and personnel, outcome assessment incomplete data, and selective reporting. Each criterion was assigned a rating of "low," "high," or "unclear." Quality assessment was completed in duplicate with discrepancies resolved through discussion. Studies were not excluded based on quality assessment.

8.2.5 *Data Analysis*

A meta-analysis was conducted for comparisons with two or more studies to inform the magnitude of treatment effect for offloading devices. Mean difference was calculated for time to ulcer healing. For studies reporting mean time to healing in weeks, estimates were converted to days by multiplying estimates by seven. For studies reporting median (IQR), we assumed normal distribution and estimated the mean to be equal to the median, and standard error was estimated by multiplying the IQR by 1.35).[78] All analyses were completed in Stata version 15.[79]

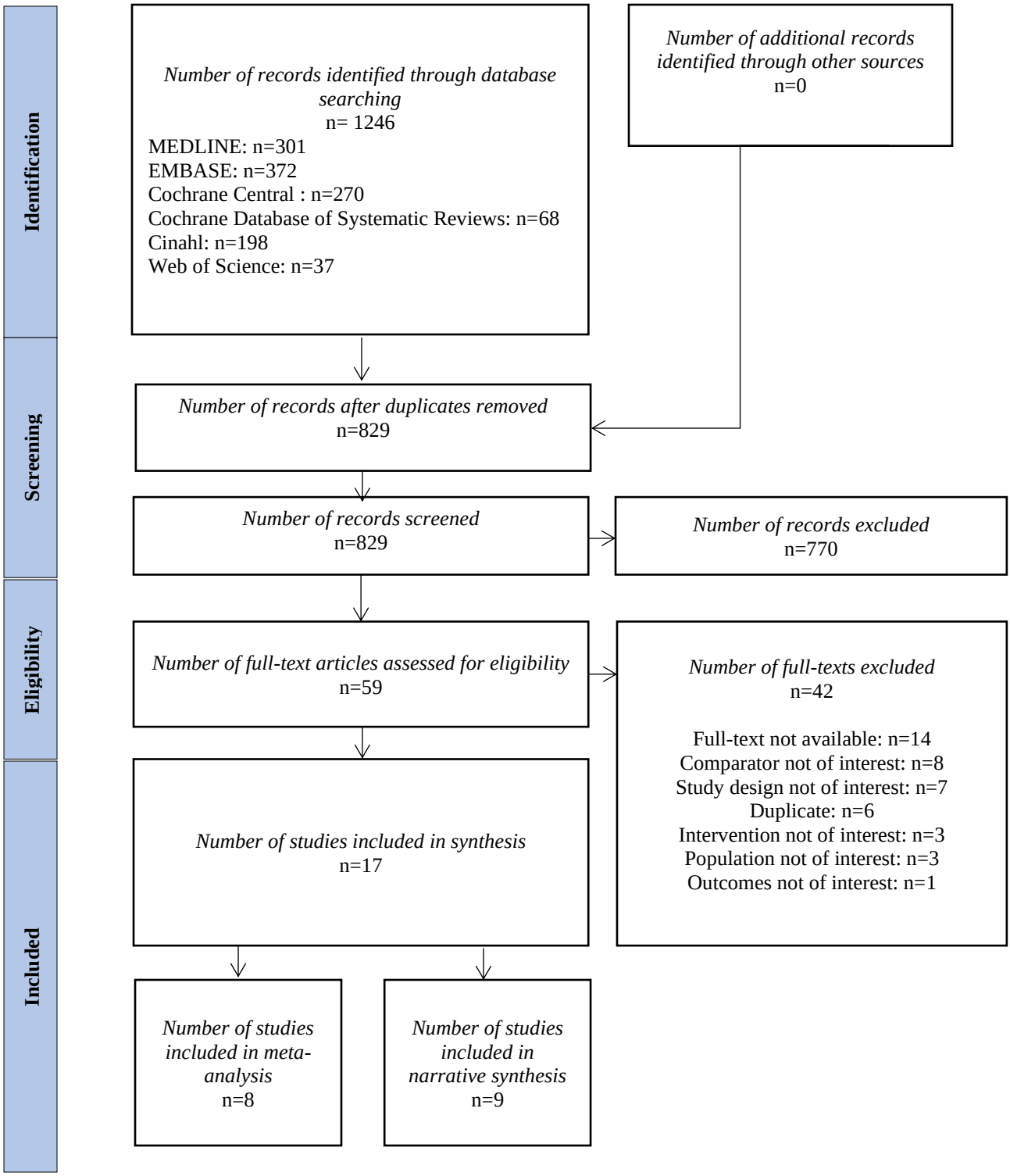
For outcomes that could not be analyzed using meta-analysis, results are synthesized in tabular and narrative formats.

8.3 **Results**

8.3.1 *Study Characteristics*

A total of 1,246 citations were identified from the literature search: EMBASE (n=372), MEDLINE (n=301), Cochrane Central (n=270), CINAHL (n=198), Cochrane Database of Systematic Reviews (n=68), and Web of Science (n=37). No additional records were identified through hand searching. After duplicates were removed, 829 unique citations were screened in abstract review, with 59 studies proceeding to full-text review. Forty-two studies were excluded in full-text review for the following reasons: full-text not available (n=14), comparator not of interest (n=8), not an RCT (n=7), duplicate (n=6), intervention not of interest (n=3), population not of interest (n=3), and outcome not of interest (n=1). For a complete list of excluded studies, see Appendix C – Systemic Review of Clinical Effectiveness Tables and Meta-Analysis. A total of 17 studies were included in this systematic review (Figure 8). [80-96]

Figure 9. PRISMA Flowchart of Included and Excluded Studies



Included studies were conducted in the United States (n=8), Italy (n=6), a joint study by the Netherlands and USA (n=1), Qatar (n=1), and Germany (n=1). There were 850 participants across the 17 included studies, ranging from 23[91] to 73[83] participants. The device examined most often was TCC (n=15), followed by with RCW (n=7) and ICW (n=5). All other devices were compared to TCC, and include: ATL with TCC,[93,94] half shoe,[82] cast shoe,[87] forefoot offloading shoe,[87] shear walker,[83] healing sandal,[83] therapeutic shoe,[88] traditional dressing treatment,[92] custom-made temporary footwear,[96] and stabil-D walker cast[90] (Table 17). Follow-up times varied from 30 days[88] to two years,[94] with many of the studies reporting outcomes at 12 weeks or 90 days (n=11).

Number of ulcers healed was reported most often (n=15), followed by time to healing (n=13), complications (n=10), and amputations (n=5). Reoccurrence of ulcer, step-down treatment, adherence, and health-related quality of life were reported in two studies, and treatment discontinuation was reported in one study. Full study characteristics are reported in Appendix C – Systematic Review of Clinical Effectiveness Tables and Meta-Analysis.

Table 18. Outcomes, by Devices Compared

	TCC	RCW
RCW	Ulcers healed[82,84,89,91]; Time to healing[82,84,89,91]; Complications[84,89]	
ICW	Ulcers healed[84-86]; Time to healing[84-86]; Amputations[86]; Complications[84-86]	Ulcers healed[81,84,95]; Time to healing[81,84]; Complications[84,81]
Healing Sandal	Ulcers healed[83]; Time to healing[83]; Patient adherence[83]; Complications[83]	
Cast Shoe	Ulcers healed[87]; Time to healing[87]; Patient adherence[87]; Amputations[87]; Treatment discontinuation[87]; Complications[87]	
Forefoot Offloading Shoe	Ulcers healed[87]; Time to healing[87]; Patient adherence[87]; Amputation[87]; Treatment discontinuation[87]; Complications[87]	
Achilles Tendon Lengthening	Ulcers healed[94]; Time to healing[94] Reoccurrence[93,94]; Step-down treatment[94]; Amputations[94]; Complications[94]	
Traditional Dressing Treatment	Ulcers healed[92]; Time to healing[92]; Amputations[92]; Complications[92]	
Custom-made Temporary Footwear	Ulcers healed[96]; Time to healing[96] Amputations[96]; Step-down treatment[96]	
Shear Walker	Ulcers healed[83]; Time to healing[83]; Patient adherence[83]; Complications[83]	
Half-Shoe	Ulcers healed[82]; Time to healing[82]	Ulcers healed[82]; Time to healing[82]
Therapeutic Footwear	Ulcers healed[88]	
Stabil-D Cast Walker	Ulcers healed[90]; Time to healing[90]	

Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

Data permitted meta-analysis with the following comparator pairs: TCC versus ICW, TCC versus RCW, and ICW versus RCW. Meta-analysis was conducted for number of ulcers healed at three months follow-up, and mean time to ulcer healing. Given the low number of included studies and the variation in devices, a random effects model was used. A random effects model assumes that the true effect size might differ study to study. Risk ratios were calculated for number of ulcers healed.

8.3.1 *Quality Assessment*

Quality assessment was conducted using the Cochrane Handbook Risk of Bias Tool (version 5.1.0).[77] Inclusion in data analysis was not based on study quality. Random sequence generation and incomplete data were mostly low risk of bias. Due to the nature of the intervention, blinding was not possible; therefore all studies were at high risk of bias for "blinding of participants and personnel." Allocation concealment, blinding of outcome assessment, selective reporting, and other biases were not clearly stated in most studies, therefore were assessed as "unclear" (Table 18).

Table 19. Quality Assessment using Cochrane Risk of Bias Tool 5.1.0

Author (Year)	Random Sequence Generation	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcome Assessment	Incomplete outcome Data	Selective Reporting	Other Bias
Piaggesi (2016)[84]							
Armstrong (2008)[80]							
Armstrong (2005)[81]							
Armstrong (2001)[82]							
Katz (2005)[86]							
Bus (2018)[87]							
Caravaggi (2000)[88]							
Caravaggi (2007)[89]							
Faglia (2010)[90]							
Gutekunst (2011)[91]							
Lavery (2015)[83]							
Mueller (1989)[92]							
Mueller (2004)[93]							
Mueller (2003)[94]							
Najafi (2017)[95]							
Van De Weg (2008)[96]							
Piagessi (2007)[85]							

Low Unclear High

8.3.2 *Ulcers Healed*

Ulcers healed was the most reported outcome, with fifteen studies reporting this outcome. Based on the number of comparators and varying follow-up times, seven of the 15 studies were included in a meta-analysis comparing TCC with ICW, TCC with RCW, and ICW with RCW at 12 weeks. Forest plots can be found in Appendix C – Systematic Review of Clinical Effectiveness Tables and Meta-Analysis.

Three studies compared TCC to ICW at 12-week follow-up[84-86] and were included in meta-analysis. Two studies favoured TCC, and one study favoured ICW; none of the estimated risk ratios were statistically significant. The pooled estimate was also statistically non-significant suggesting that TCC and ICW are equivocal for ulcers healed (RR: 1.06, 95% CI: 0.93 to 1.20) (Table 19).

Four studies reported ulcers healed for TCC to RCW with sample sizes ranging from 23[91] to 58.[89] Three studies reported ulcers healed at 12 weeks and were included in the meta-analysis. The pooled analysis was not statistically significant, suggesting that TCC and RCW are equivocal for ulcers healed (95% CI: 0.99 to 1.36). One of the four studies, Gutekunst et al.[91] did not report a follow-up time and was therefore excluded from meta-analysis; results from this study favoured TCC (9/11 healed) compared to RCW (5/12 healed), with a statistically significance ($p<0.05$) (Table 19).

Three studies compared ICW to RCW.[81,84,95] All studies favoured ICW over RCW, and resulted in a statistically significant pooled analysis. This result suggests that at 12 weeks, ICWs are 1.4 times more likely to result in ulcer healing than RCWs (95% CI: 1.0 to 1.97) (Table 19).

Table 20. Summary of Meta-analysis, Ulcers Healed at three month follow-up

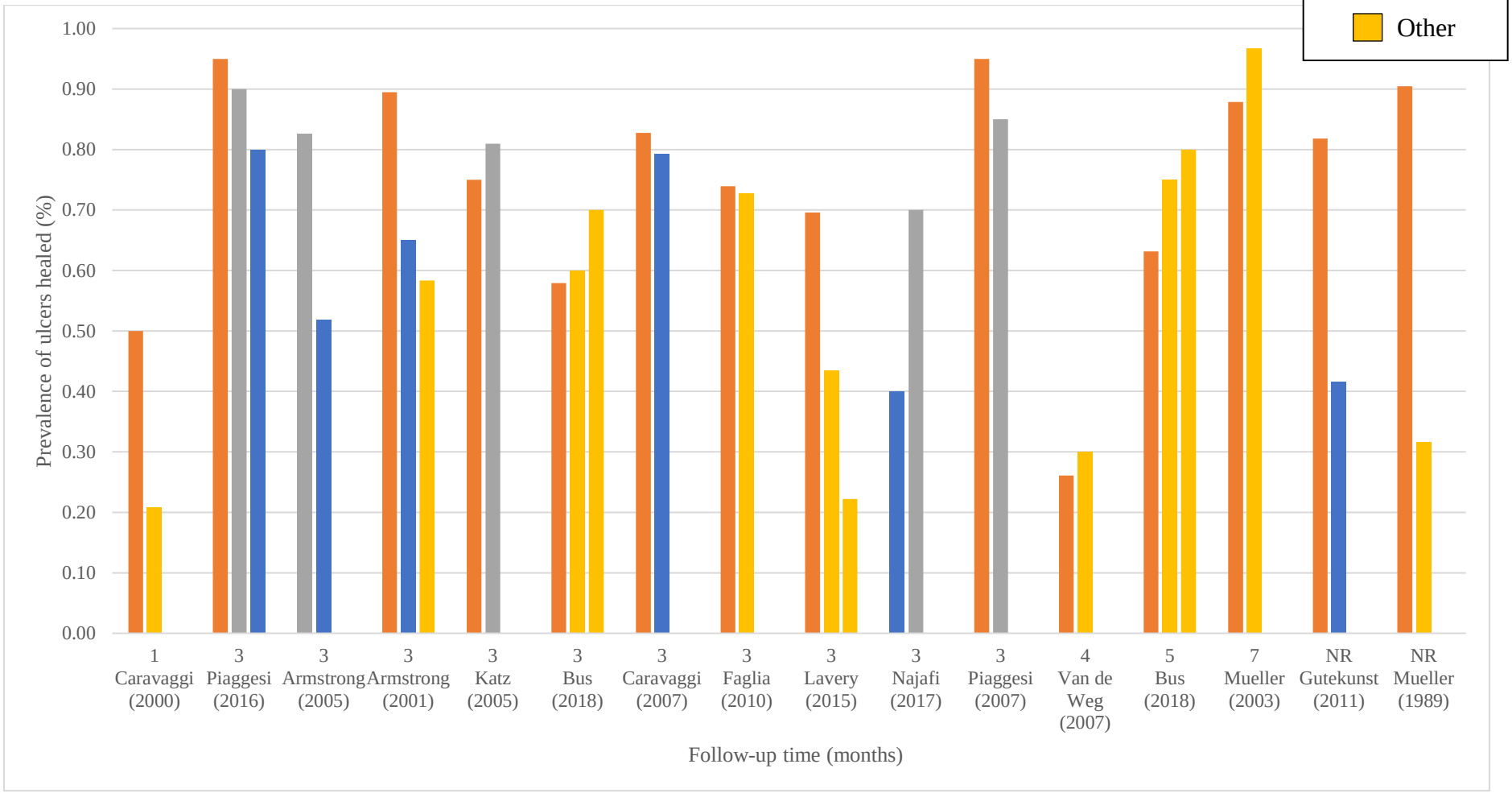
Comparators	**Pooled Estimate**	**Confidence Interval**	**Heterogeneity (I^2)**
TCC and ICW	1.06	0.93 to 1.20	0.0%
TCC and RCW	1.16	0.99 to 1.36	0.0%
ICW and RCW	1.40*	1.0 to 1.97	54.3%

*Statistically significant result ($p<0.05$).
Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

In addition to TCC, ICW, and RCW, ten additional comparators were reported. Each of these comparators was reported by only one study, making meta-analysis not possible. All other comparators were compared to TCC. At one month follow-up, there were more ulcers healed for TCC than therapeutic shoe;[88] at three month follow-up, there were more ulcers healed for TCC than half-shoe,[82] stabil-D cast walker,[90] healing sandal and shear walker.[97] At unknown follow-up time, there were more ulcers healed for TCC than traditional dressing treatment.[92] Compared to TCC, the following comparators reported a higher prevalence of ulcer healing: cast shoe and forefoot offloading shoe at both three and five month follow-up,[87] custom-made temporary

footwear at four month follow-up[96] and TCC plus ATL surgery at seven month follow-up[94] (Figure 9).

Figure 10. Number of Ulcers Healed, by Study, Device, and Follow-up Time



Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

8.3.3 *Mean Time to Healing*

Mean time to ulcer healing was measured in 13 studies. Six studies compared TCC versus ICW, TCC versus RCW, and TCC versus RCW; meta-analysis was possible for these comparators. Forest plots can be found in Appendix C – Systematic Review of Clinical Effectiveness Tables and Meta-Analysis. The additional seven studies are narratively synthesized.

Three studies compared TCC to ICW.[84-86] Mean healing times ranged from 35 to 45.5 days for TCC, and 28 to 45.9 days for ICW. Results were mixed with two studies favouring TCC, and one study favouring ICW. No estimates were statistically significant, suggesting that TCC and ICW are equivocal for mean days to ulcer healing (SMD: -0.01; 95% CI: -0.4 to 0.37) (Table 20).

Three studies compared TCC to RCW.[82,84,91] Mean time to healing ranged from 33.5 to 95 with TCC, and 43.2 to 94 with RCW. The pooled standardized mean difference is not statistically significant, suggesting that TCC and RCW are equivocal for mean days for ulcer healing (-0.96; 95% CI: -2.48 to 0.55). Heterogeneity of this result is high (I^2=88.0%) (Table 20).

Two studies compared ICW to RCW.[81,84] Mean time to healing were similar for ICW (39.6 and 41.6 days), however, the range was wider for the RCW participants (43.2 and 58 days). The pooled estimate was non-significant, suggesting that ICWs and RCWs are equivocal for mean days to ulcer healing (SMD: -0.59; 95% CI: -1.26 to 0.08) (Table 20).

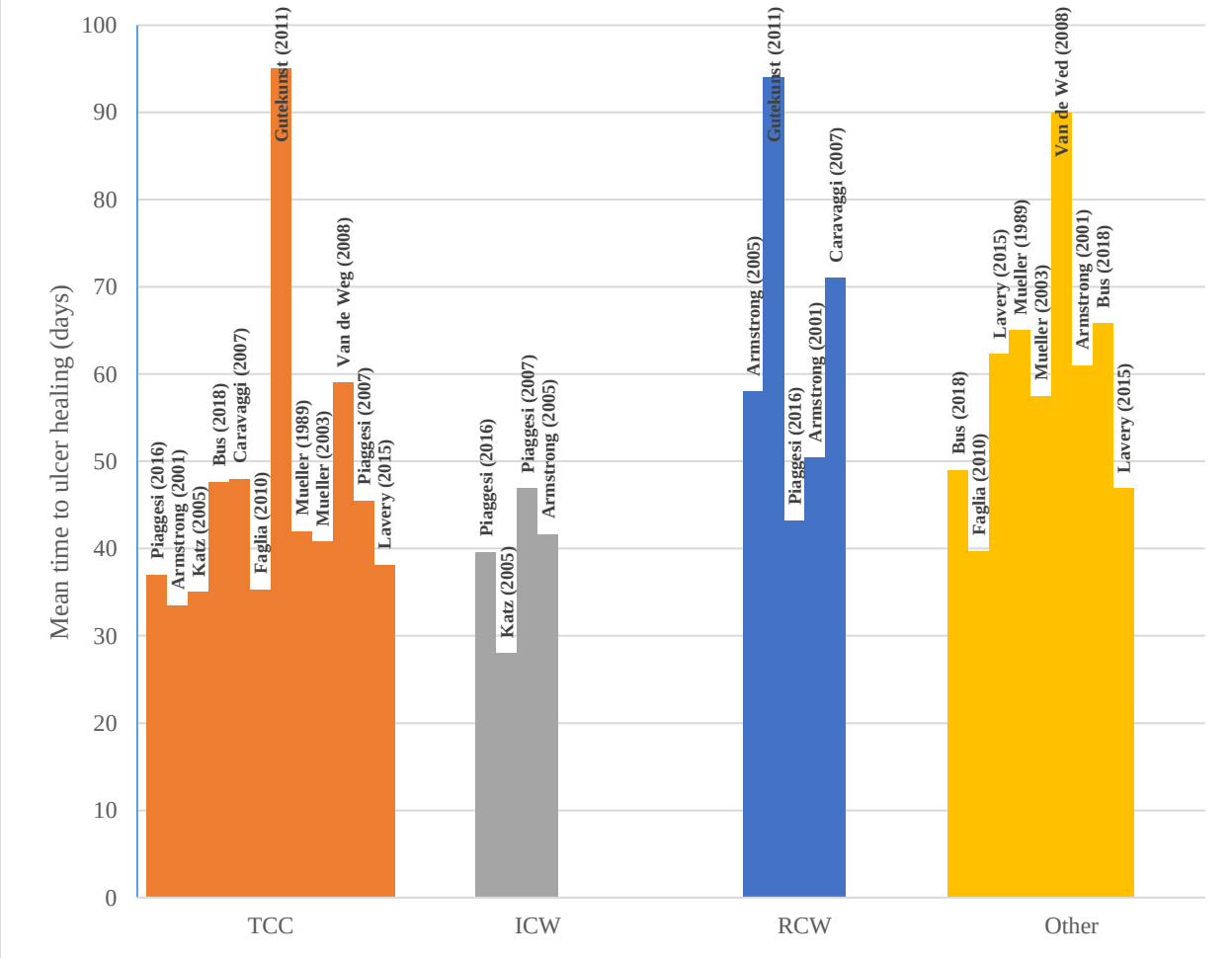
Table 21. Summary of Meta-analysis, Mean time to Healing

Comparators	**Pooled Estimate (Standardized Mean Difference)**	**Confidence Interval**	**Heterogeneity (I^2)**
TCC and ICW	-0.01	-0.4 to 0.37	0.0%
TCC and RCW	-0.96	-2.48 to 0.55	88.0%
ICW and RCW	-0.59	-1.26 to 0.08	44.8%

Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

Nine additional comparators were examined in time to healing. The range in mean healing time was 33.5 to 95 days for TCC, 28 to 46.9 days for ICW, 43.2 to 94 days for RCW, and 39.7 (stabil-D walker cast) to 90 days (custom temporary footwear) for all other devices. Ten of the 13 studies did not report statistical significance, or reported non-significant findings. In two studies, mean time to healing for TCC was significantly less than RCW and half shoe,[82] and the healing sandal.[83] In one study, ICW had a significantly shorter mean time to healing than RCW.[81] Overall, it appears that ICW yielded the shortest mean time to healing, however given the differences on how results were reported (days versus weeks), sample sizes, and the limited number of studies, it is not possible to make any meaningful comparisons between devices (Figure 10).

Figure 11. Mean time to Ulcer Healing, by Device. Each bar represents estimate from one study.



Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

8.3.4 *Complications*

Complications were reported in nine studies. Infection,[81,83,85,89,92,94] abrasions,[84,86,87,94] second ulcers,[86,87,94] and falls[86,87,94] were the most frequently reported complications. Due to inconsistencies in the reporting of complications, this data did not permit meta-analysis, and is rather, summarized in Table 21.

Table 22. Complications

Author (Year)	Device	Complications (number of events)													
		Total Complications (n)	Abrasion (n)	Rupture of TCC (n)	Maceration (n)	Trauma of contralateral foot (n)	Fungal intertrigo (n)	Infection (n)	Broken cast (n)	Second ulcer (n)	Falls (n)	Hospital admissions (n)	Blister (n)	Pressure point (n)	Other (n)
Piagessi (2016)[84]	**TCC** (n=20)	7	4	3	0	0	0								
	ICW (n=20)	2	0	NA	1	1	0								
	RCW (n=20)	1	0	NA	0	0	1								
Armstrong (2003)[81]	**ICW** (n=23)	21			15			6							
	RCW (n=27)	16			9			10							
Katz (2005)[86]	**TCC** (n=20)	16	2		7				3	2	0				2
	ICW (n=21)	9	0		6				1	1	1				0
Bus (2018)[87]	**TCC** (n=20)	14	2							1	1	2	2	6	
	Cast Shoe (n=20)	10	4							2	0	1	1	2	
	Forefoot Offloading Shoe (n=20)	9	1							0	1	0	3	1	
Caravaggi (2007)[89]	**TCC** (n=29)	5						5							
	RCW (n=29)	6						6							
Lavery (2015)[83]	**TCC** (n=23)	1						1							0

Author (Year)	Device	Complications (number of events)													
		Total Complications (n)	Abrasion (n)	Rupture of TCC (n)	Maceration (n)	Trauma of contralateral foot (n)	Fungal intertrigo (n)	Infection (n)	Broken cast (n)	Second ulcer (n)	Falls (n)	Hospital admissions (n)	Blister (n)	Pressure point (n)	Other (n)
	Healing Sandal (n=23)	3						3							0
	Shear Walker (n=27)	5						4							1
Mueller (1989)[92]	**TCC** (n=21)	0						0							
	Traditional Dressing Treatment (n=19)	3						3							
Mueller (2003)[94]	**TCC** (n=33)	6	6					0		0	0				
	TCC with ATL (n=31)	11	4					1		4	2				
Piagessi (2007)[85]	**TCC** (n=20)	4		1	2			1							0
	ICW (n=20)	7		NA	4			1							2

Abbreviations: ALT: Achilles tendon lengthening; ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

8.3.5 *Number of Amputations, Patient Adherence, Treatment Discontinuation, Reoccurrence, and Step-Down Treatment*

Additional outcomes of interest included: number of amputations, patient adherence to device, treatment discontinuation, reoccurrence of ulcers, and step-down treatment. Additional outcomes were reported in seven studies. The most often reported outcome was amputations.[86,87,92,94,96] Reoccurrence,[93,94] patient adherence,[83,87] and step-down treatment[94,96] were reported in two studies each, and treatment discontinuation was reported in one study.[87] Eight amputations were reported across five studies. Half of these amputations were reported in TCC participants, two in traditional dressing treatment, and one in ICW and cast shoe participants. Mueller et al.[92] reported that traditional dressing treatment was statistically different than TCC reported two amputations, versus zero for TCC. In another study, there were significantly more patients who discontinued treatment using TCC vs. cast shoe (35% in TCC vs. 0% in cast shoe).[87] Finally, reoccurrence of ulcers at seven months and after 2 years of were significantly less for patients who underwent ATL in addition to TCC, compared to TCC alone (Table 22).

Table 23. Number of Events of Additional Outcomes, by Study

Author (Year)	Device	Amputations	Patient Adherence	Treatment Discontinuation	Reoccurrence	Step-down Treatment
Bus (2018)[87]	TCC	1/20 (5%)	9/11 (82%)	12 weeks: 7/20 (35%) 20 weeks: 8/20 (40%)		
	Cast Shoe	1/20 (5%)	9/10 (90%)	12 weeks: 0/20[a] 20 weeks: 3/20 (15%)		
	Forefoot Offloading Shoe	0/20	12/13 (92%)	12 weeks: 3/20 (15%) 20 weeks: 3/20 (15%)		
Katz (2005)[86]	TCC	1/20 (5%)				
	ICW	1/20 (5%)				
Lavery (2015)[83]	TCC		23/23 (100%)			
	Healing Sandal		23/23 (100%)			
	Shear Walker		24/27 (89%)			
Mueller (1989)[92]	TCC	0/21				
	TDT	2/19[a] (11%)				
Mueller (2004)[93]	TCC				8 months: 5/13 (38%)	
	TCC+ATL				8 months: 3/14 (21%)	
Mueller (2003)[94]	TCC	1/33 (3%)			7 months: 16/27 (59%) 2.1 years: 21/26 (81%)	3/33 (9%)
	TCC+ATL	0/31			7 months: 4/27[a] (15%) 2.1 years: 10/26[a] (38%)	0/33
Van De Weg (2008)[96]	TCC	1/23 (4%)				1/23 (4%)
	Custom Temporary Footwear	0/20				NA

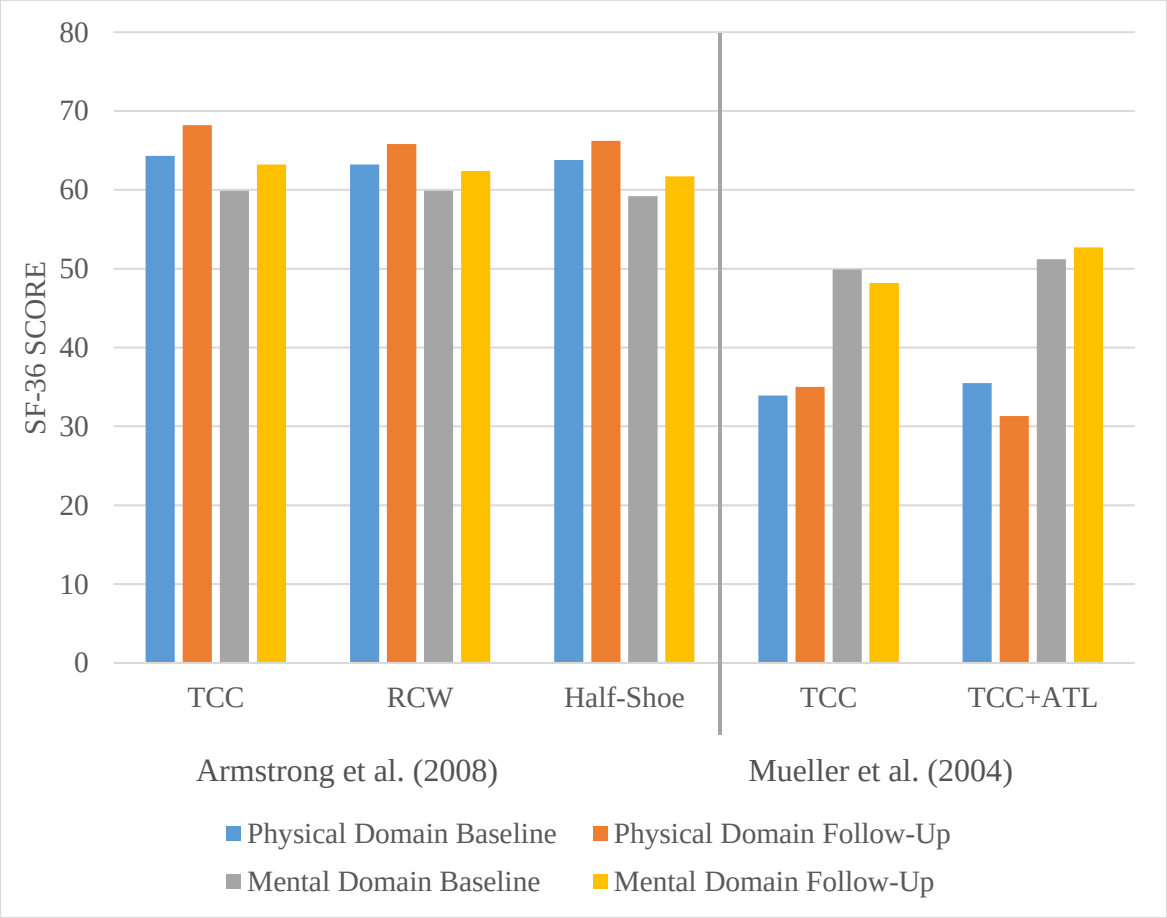
[s] Significantly different than TCC ($p<0.05$)

Abbreviations: ATL: Achilles-tendon lengthening; ICW: irremovable cast walker; NA: not applicable; RCW: removable cast walker; TCC: total contact casting

8.3.6 *Health Related Quality of Life*

Health related quality of life outcomes were reported in two studies.[80,93] Both studies reported physical and mental domain scores using the SF-36 questionnaire. Comparisons were made between TCC, RCW and half-shoe, and TCC versus TCC with ATL surgery. After 12 weeks, follow-up scores tended to improve for both physical and mental domain scores. Follow-up physical scores for TCC with ATL surgery decreased slightly[93] (Figure 11).

Figure 12. Baseline and Follow-up Scores for Health Related QOL



Abbreviations: ATL: Achilles tendon lengthening; ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

8.4 Conclusions

Seventeen studies were identified that explored the clinical effectiveness and safety of offloading devices including TCC, ICW, and RCW. Study quality of included studies were equivocal with all but one study[83] reporting high risk of bias for at least domain. Studies were not excluded based on study quality. Data permitted meta-analysis for two outcomes: ulcers healed and time to ulcer healing. Meta-analysis compared TCC with ICW, TCC with RCW, and ICW with RCW.

The results from meta-analysis were mostly equivocal for both number of ulcers healed, and time to ulcer healing, with the exception of ICW and RCW for ulcers healed. Data suggests that ulcers are 1.4 times more likely to heal within 12 weeks when using ICW versus RCW (95% CI: 1.0 to 1.97). The limited number of studies, and the modest sample sizes, may have contributed to the non-significant findings in meta-analysis.

For outcomes that were unable to be pooled, narrative synthesis was provided. Complications were reported in nine studies. Given the variety of complications reported, comparisons between devices was not possible. Other outcomes such as amputations, step-down treatment, treatment discontinuation, patient adherence, and reoccurrence were reported in seven studies. With very little overlap in reporting, we were unable to draw any conclusions between devices. Lastly, health-related quality of life outcomes were reported in two studies with four different devices, therefore, we were unable to draw any meaningful conclusions between devices.

There are notable limitations to this review. With few studies comparing each device, and small sample sizes, it is not possible to make a statistical comparison between all of the devices for clinical, safety, and quality of life outcomes. The variety of offloading devices considered in the literature limited our meta-analysis to the three most reported comparators (e.g., TCC, ICW, and RCW) for the two most reported outcomes (e.g., ulcers healed and mean time to healing).

9 Rapid Review of Patient Perspectives on Offloading Devices

Summary

- A rapid review of the qualitative literature on patients' and healthcare providers' perspectives on offloading devices was conducted by CADTH.
- 12 studies met the inclusion criteria and were included in the CADTH report.
- Patients and podiatrists identified the following barriers to adherence of offloading devices: mobility and autonomy, device mechanics, perceptions of the device's effectiveness, self-image and restoring social normalcy, device cost, and lack of information.
- A collaborative discussion between healthcare providers and their patient to allow for shared decision making in choice of offloading device may allow for better device adherence

9.1 Purpose

To summarize the findings of a rapid review of the qualitative literature on health care providers and patient perspectives on offloading conducted by the Canadian Agency for Drugs and Technologies in Health.

9.2 Overview of CADTH Methods

A rapid review of the qualitative literature on patient perspectives was conducted by the CADTH on behalf of the HTA Unit at the University of Calgary. The rapid review sought to describe the experiences and perspectives of people with type 1 or type 2 diabetes with neuropathic foot ulcers, their partners or spouses, and their health care providers on offloading devices.

9.2.1 *Literature Selection*

A literature search was conducted by an information specialist in Ovid MEDLINE and Scopus and was limited to English language and studies published between January 1, 2010 and May 5, 2020. One reviewer screened citations, selected studies, and assessed for quality using Quality of Reporting (QuaRT) tool as a guide. A qualitative meta-synthesis methodology was used to analyze results. Using the constant and comparative method and constructivist grounded theory, the reviewer retrieved, compared, and synthesized findings to develop an overall interpretation of the themes and concepts captured in the included studies.

9.3 **Summary of Results**

Twelve studies met the inclusion criteria and were included in the CADTH report: eight qualitative only and four mixed- or multi-methods. Ten studies included patient populations, and two included healthcare provider (podiatrists) experiences with and perspectives on offloading devices. Eight studies identified offloading device of interest; four were interested in shoe insoles or padded heels, two in TCC or iTCC, one in RCW and ICW, and one on multiple unspecified non-removable offloading devices. Nearly all included a clear research question and study approach, however fewer studies provided sufficient descriptions of other methodological characteristics in regards to data analysis.

9.3.1 *Patients' Perspectives*

There are many challenges that patients face in their day-to-day lives while using offloading devices resulting in barriers to consistent and long-term device adherence. Patients in six studies reported lacking essential information for offloading device use including information on: device function, inflating air bags in RCW, general advice on foot care, relationship between ulceration and device, using footwear in wet weather, and other self-care practices to accompany offloading device use.

Some patient's mobility and autonomy were limited due to the heavy and bulky nature of offloading devices, while others believed that it increased due to previous restrictions by the ulcer. Due to major inconvenience or cultural and family norms, patients generally did not wear offloading devices in their homes. Patients expressed challenges with navigating the offloading device mechanics, like the air bags and straps on RCW. However, they were still preferred due to ease of application and removability and no requirement of regular appointments with healthcare professionals, unlike TCC. Patients also expressed anxiety with TCC due to inability to perform wound and dressing checks.

Patient's perceptions of the device's effectiveness varied. Some patients expressed an expectation in its ability to prevent and heal ulceration quickly; when these expectations were not met, device adherence decreased. Others' expectations of healing were overshadowed by

concerns for unintended health outcomes such as change in walking, perceived increased risk of fall, development of new ulcers, and gait problems resulting in hip and other injuries.

Patients' sense of importance of ulcer healing was outweighed by concerns with self-image and self-presentation. Self-image depended on beliefs about how device provide "normal" function in everyday activities. This included the desire to fit in with the social normalcy of family, friends, and the community. Offloading devices were viewed as a symbol of disability and were not aesthetically pleasing or fashionable. Device adherence increased when family and friends understood the value of the device and alleviated the social concerns.

Patients' preference for an offloading device were affected by costs and insurance coverage. Indirect costs include materials and clinic visits, as well as transportation and travelling costs. Patients also expressed concern with the costs associated with changing offloading devices to achieve better outcomes as recommended by their healthcare providers when previous devices did not yield expected healing rate. Device repair concerns were also a factor and more prevalent for therapeutic footwear and orthotics as they deteriorated quicker than RCW.

9.3.2 *Health Care Provider Perspectives*

Podiatrist concerns and experiences with offloading devices mirrored patients' perspectives and challenges. Podiatrists recognize factors that reduce device adherence include lack of improvement in ulcer healing, device costs, bulkiness and weight, lifestyle, physical, psychological, and religious or cultural barriers. Their approach in device recommendations varied, some selected the most aggressive device such as TCC, favoring healing over patient preferences for convenience and retaining mobility and autonomy in daily lives. Others initially selected a moderate offloading device and increased to an aggressive modality when there was no improvement. Podiatrists reported barriers to providing complete services to patients as being 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.

9.3.3 *Recommendations for Improving Offloading Device Adherence*

Patients in six studies mentioned desire to have greater freedom and participation in decisions relating to their care and device use. Therefore, a collaborative discussion between healthcare providers and patients may aid in recognizing and incorporating patient preferences in device-related decisions that may also increase sustained adherence. By understanding how patients might use the offloading device in their daily lives, connecting it to patients' sense of well-being and function, focusing on patients' social and familial goals in relation to treatments, and integrating device into daily routines, this collaborative relationship may also facilitate patients' acceptance of the device into their daily lives. Patients preferred shoes that were quick to wear, comfortable and soft, lightweight, appropriately sized with adequate ventilation, and improved ability to see the ulcer. Some patients identified their ideal device would be: lightweight with Velcro fastening, molded foot bed, cleated rubber outsole, close fitting, tight laces, increased tread, rigid sole, soft shoe insole, and waterproof.

9.4 **Conclusions**

The findings of this review identified several barriers that patients face in offloading device adherence: mobility and autonomy, device mechanics, perceptions of device's effectiveness, self-image and restoring social normalcy, device costs, and lack of information. Podiatrists' perspectives and experiences mirror patients' concerns. Podiatrists had two approaches to care, either selecting aggressive modalities that changed when there were adverse outcomes, or selecting moderate modalities that changed to aggressive ones if healing rate was not ideal. Patients expressed a desire for collaborative discussions between the healthcare providers and themselves to allow for shared decision making in offloading device decisions. They also recommended suggestions to improve the design of the offloading devices to minimize the disruption to their daily routine and allow for improved device adherence. None of the included studies examined patient perspectives in the context of BC; therefore, patient interviews within this context were required for policy decision-making.

10 Patient Interviews

Summary

- Finding effective offloading care in BC was a lengthy process, which was often characterized by months of ineffective treatments, sometimes leading to infection and deterioration.
- Patients who had received TCCs reported observing their foot ulcer healing very quickly and were grateful to have finally received effective treatment.
- Offloading devices were reported to impact patients' mobility, sleep, ability to shower, were associated with high cost and time-commitment for appointments, and resulted in stigma.
- Although most patients reported following treatment recommendations for wearing their offloading devices for the initial healing, some struggled to wear their maintenance devices, which led to re-ulceration.
- Patients reported wishing for more coverage of offloading devices in BC, as well as more accessibility to certain devices (primarily TCCs), and more education around the seriousness of the condition, options available, and what could happen if they do not wear the devices.

10.1 Purpose

To understand the patient experience with offloading devices for treatment and prevention of diabetic neuropathic plantar foot ulcers in BC.

10.2 Methods

10.2.1 *Data Collection*

A convenience sampling strategy was used to identify participants within the professional networks of podiatrists and clinicians, including former or current patients.[98] Clinicians and physicians were provided with a recruitment poster which contained information about this research. Criteria for inclusion were: over 18 years of age; DFU diagnosis; received treatment for their foot ulcer in BC; and, used or are using pressure-relieving (offloading) devices as part of their treatment.

A semi-structured interview guide was developed to support the process. This *a priori* guide included questions on:

i. experience with diabetic foot ulcers,
ii. experience with offloading devices,
iii. the treatment process, and

iv. experience with other devices.

This guide evolved over the course of the interviews, as questions were refined to reflect what had been learned through the previous interview(s). Prior to the interview, participants were given information about the project, a demographic form, and a consent form. Participants were encouraged to ask questions and were reminded that they were able to take a break during the interview, postpone the interview, leave the interview, or withdraw their consent to participate at any time. All participants were given the choice to provide either written or verbal consent.

This study received ethics approval (REB20-0368) by the Research Ethics Board of Alberta (REB) at the University of Calgary. The full interview guide can be found in Appendix D – Patient Interview Questions.

10.2.2 *Analysis*

All interviews were conducted by an experienced PhD-trained researcher, audio-recorded with the consent of the interview participants, and detailed notes were taken. The interviews were then transcribed for analysis.

The data were analyzed using the framework analysis methodology,[99,100] a form of qualitative content analysis, which is used to draw descriptive conclusions based on themes. Originally developed for policy research, this qualitative methodology is particularly useful for synthesizing data in order to support policy questions. Framework analysis involves categorizing data according to key issues and themes[100] and broadly involves seven stages: 1) transcription of the interviews; 2) familiarization with the interviews; 3) coding the interviews; 4) developing a working analytical framework; 5) applying the analytical framework to the existing categories and codes; 6) charting the data into the framework matrix; and 7) interpreting the data.[99]

After the interview transcription and familiarization processes were completed, the interviews were coded in QSR's International NVivo 12 qualitative data analysis software.[101] Data were coded by a single reviewer and verified by a second reviewer. Discrepancies between reviewers during this process were resolved through consensus. A working analytical framework that fit the

interview data was developed and subsequently applied to the existing categories and charted in NVivo 12. Peer-debriefing was performed throughout all phases of the analysis process, following best-practice criteria set forth by Nowel et al. 2017.[102]

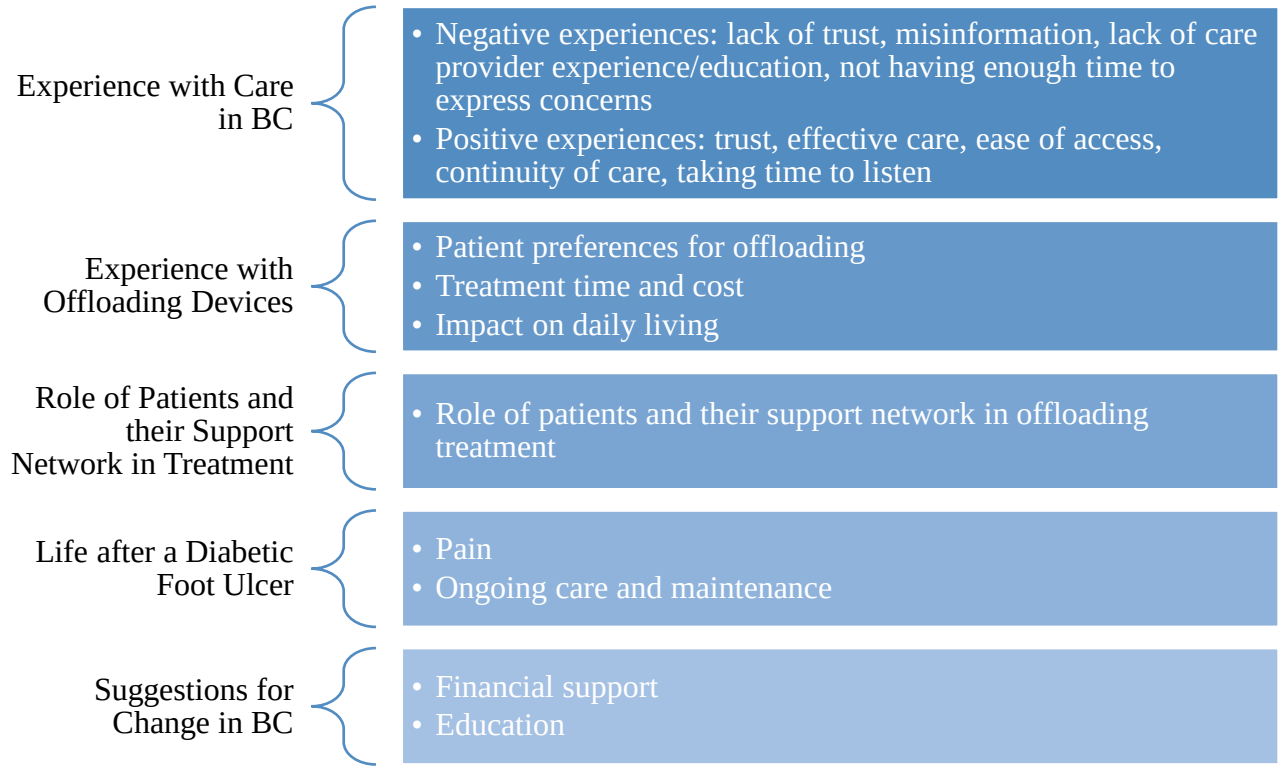
10.3 **Findings**

10.3.1 *Participants*

Eight telephone interviews were conducted from May 27 to June 10, 2020. The interviews ranged from 63 to 87 minutes in length. Eight participants completed a demographic form. Participants were between the ages of 25-34 (n=2), 45-54 (n=2), 55-64 (n=3), and 65-74 (n=1). An equal number of men and women (n=4) participated. Seven participants identified as White, and one individual identified as First Nations. Four participants had some college, no degree; two had less than a high school diploma; one participant had an associate degree; and one had a bachelor's degree. Three participants indicated they were single, three were married, one was divorced, and one was separated. Four participants were unable to work, two were employed full-time, one was unemployed but looking for work, and one was retired. When asked about their annual household income before tax, five participants indicated they earned less than $20,000, one participant earned between $40,000 and $59,999, one participant indicated earnings between $60,000 and $79,999, and one indicated over $100,000. Five participants were from the Interior Health Authority and three participants were from the Fraser Health Authority. After the telephone interviews were completed, an additional participant provided their written responses to the interview guide via e-mail; the participant did not complete the demographic information form.

The following five themes were identified in the analysis: experience with care in BC, experience with offloading devices, role of patients and their support networks in treatment, life after a DFU, and suggestions for change in BC (Figure 12).

Figure 13. Themes and Subthemes in BC Patient Interviews



10.3.2 *Experience with Care in BC*

10.3.2.1 Negative Care Experiences

Several patients reported receiving ineffective care for several months prior to finding a care provider they trusted; these patients expressed frustration with these initial challenges of receiving inadequate care (Figure 13). Many patients described months of daily wound dressing changes and long-term antibiotic treatment for infection until they heard about or sought out a specialist who fit them with an offloading device. Some patients received offloading care during a hospital admission for other comorbid health issues, others had to seek it out on an outpatient basis. One patient reported learning about an offloading specialist from one of the nurses while receiving intravenous (IV) antibiotics. Another patient found their current offloading provider through a Google search after receiving months of ineffective care.

Aside from struggling to receive timely and effective care, patients broadly described experiencing difficulties associated with following care advice from not well-informed health care providers. Notably, some patients experienced deterioration after following treatment

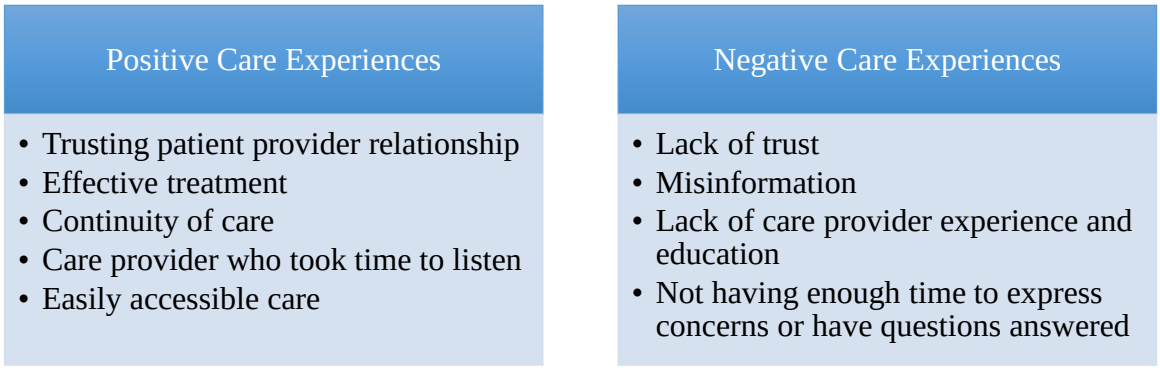
recommendations they received from a health care provider. One patient reported that their DFU got infected after they were told to soak their foot in Epsom salts; after a course of IV antibiotics and wearing a therapeutic shoe that led to healing, they experienced re-ulceration from wearing orthotics they were prescribed. The same patient also reported not knowing that they needed to stay off their foot: *"I think I did the most damage to the foot walking on it. My own doctor didn't understand what Charcot foot was. I had to take him a brochure and let him read it. They should've known right off the bat. I should've never been walking of any sort. Nobody told me that. Nobody. It went on for a year and nobody told me that."* Another patient had several toes amputated after wearing a prescribed orthotic, due to poor fit. There was a sense across these patients that, once their DFU reached a certain stage, things spiraled out of control very quickly.

One patient reported being skeptical of the medical advice they received that suggested they wear orthotics while their DFU was not yet healed. The patient reported "not feeling right" about this medical advice and opted to continue using wound dressings to try to heal their DFU: "*So I just got frustrated and then I kind of kept doing it myself, because I realized that these doctors are not really doing much for me. The only thing that helped was antibiotics and that was to just basically get the wound under control, essentially, so it's not pushing and it's not doing all sorts of bad things, right?"*

10.3.2.2 Positive Care Experiences

Patients also reported being very grateful after finding an offloading care provider that could help them heal their DFU (Figure 13): *"… he healed me. I can't say enough about him. He's just an ordinary guy but he's a doctor."* Also important to patients was having a trusting patient-provider relationship, having a care provider who took the time to listen to their concerns, experiencing continuity of care, and having easily accessible care: *"I love her. She is wonderful. I can pick up the phone and call her or pop her an email if I'm having difficulties. As I say, [my doctor] is great. That team over there…it was fabulous."*

Figure 14. Positive and Negative Experiences with Care in BC



10.3.3 *Experience with Offloading Devices*

10.3.3.1 Patient Preferences for Offloading

Patients reported trying wound dressings, orthotics, therapeutic shoes with inserts, air boots, and total contact casts (TCCs), often trying several devices within their treatment course. The four patients who had received TCCs generally reported it to be the most effective offloading device in their experience. There was a sense across some of these interviews that TCCs were the "last resort", with patients desperate to find a treatment that works. Most of these patients ended up in TCCs after five to seven months of unsuccessful treatment. None of the patients who had TCCs were aware of them before they got them, but all were surprised by the effectiveness they observed: *"At first it was like what's this guy doing? And then after a couple, two or three weeks, it was like he's going, "Hey this is working good. This is what we needed to do. That's what someone should've done a long time ago."* One patient described their TCC experience after wound dressings as follows: "*So, after nine months of nothing, then four weeks, boom."* Several patients expressed wishing they could have received the TCC sooner and felt that TCC would be their treatment of choice in the event of re-ulceration:

> *"Oh. I tried just dressing the wounds, I've tried antibiotics, and just dressing the wound right with bandages, I've tried the PICO 7 [negative pressure wound therapy], many, many, many times. In the end, it's always the same result...if I had this come again, I would just turn around and say, "I don't want to do anything else just to put a cast on it."*

The five patients who did not end up in a TCC achieved healing of their DFU with varying degrees of success. Some of them reported a relatively unremarkable healing trajectory, whereas others reported deterioration of their condition that included pain, and in some cases, amputation. Given that these patients used different offloading devices, no device emerged as preferential across patients.

Most patients were generally satisfied with the offloading device they received and felt that it was a worthwhile investment: *"[…] having the offloading shoe made a huge difference in my ability to be mobile, especially in the wintertime. So yeah, I go, "It's an investment in my health and it's an investment in my mental health."* However, one patient reported experiencing significant pain after offloading and expressed regret about undergoing the treatment on pain after offloading. Several patients reported wanting to have surgery to fix the bone in their foot that is causing the pain, but being scared to go through with it because the success of surgery in diabetic patients is low; as a result, these patients reported feeling that offloading was the only treatment option for them.

Patients reported being prescribed different offloading devices for maintenance, which included therapeutic shoes, sandals with removable insoles, orthotics, and walkers. Aside from the challenges associated with having to wear these maintenance devices indefinitely, patients did not express strong preferences for one device over another.

10.3.3.2 Treatment Time and Cost

TCCs were generally reported to be the most expensive and time-consuming offloading device, associated with lengthy and frequent appointments. Patients who had TCCs reported going to the clinic to get them changed weekly for a duration of several weeks, with one patient reporting having to go in three times per week initially. One patient reported having to take four weeks off work while they were in a TCC.

Most patients reported that they lived a relatively short (15-20 minutes) drive away from the clinic and had a partner who could drive them to their appointments. However, one patient described driving 45 minutes to their appointments; for this patient, who did not have a partner to

drive them, the time and travel commitment were barriers that prevented them from getting TCC: *"So, I just thought, wow, I'm making enough trips as it is. And I couldn't drive myself. I had to get somebody to drive me. So, it was always a three or a four-hour affair. Sometimes I was in the hospital for five hours and he would wait for me and wait and wait and wait."*

Some patients reported having the cost of their offloading devices and treatment visits covered by their insurance provider. However, two patients living below the poverty line described paying out-of-pocket for their treatment; costs ranged from $4,000 to $5,700 for a variety of offloading devices. One of them reported having to borrow money from their friends and family to help cover the cost of their TCC. Patients who had offloading shoes reported paying from $250 to $2,000 per pair. For those who did not have insurance coverage or other funding, the cost of offloading treatment was reported to be the biggest challenge. Many felt that the high cost was justified because of the effectiveness they had experienced: "*I either choose to put myself at risk with a pair of crutches and probably end up being in a longer recovery, or I go without certain other things that I would normally maybe spend some money on."* Across interviews, patients expressed concern for other patients who may not be able to afford the treatment because of the high cost.

10.3.3.3 Impact on Daily Living

10.3.3.3.1 Showering

Showering was reported to be problematic with non-removable offloading devices, such as TCCs which cannot get wet (Figure 14). To prevent TCCs from getting wet while showering, patients used creative solutions, including covering their TCC with bags and rubber bands, lowering themselves into the bathtub with their legs hanging over the edge of the tub, and using a shower bench. There was a sense of embarrassment associated with these workaround methods. As one patient reported:

> *"We had to buy one of those... It made me feel really old, but one of those shower benches, sticks halfway out the shower, halfway on. And then you, from Shoppers, they've got these things called leg sleeves. So, it's basically a big plastic, it looks like a sock, like a Christmas stocking, looks like that, but it's*

plastic and it goes over top and it seals around the top of your calf. So those things are amazing. And then you basically have to sit down on the bench, scoot over. And you have to have one of those wands in the shower and you just shower sitting down like an old fart."

10.3.3.3.2 Mobility

Non-removable offloading devices, such as TCCs, were reported to be heavy and difficult to walk in, causing balance issues for the patients (Figure 14): *"So these casts, basically it was like wearing high socks that were like 10 pounds each, you know?"* As a result, patients (particularly those with TCCs) generally reported being confined to their home for several weeks until their DFU healed. Mobility was also reported to be impacted by removable offloading devices, with one patient discussing the difficulties of getting around using crutches during the winter.

Patients wearing removable offloading devices found it difficult to put the device on and take it off, particularly if they were obese and the device was bulky. Because of these difficulties, some patients would not put it on for walking short distances, such as going to the bathroom at night. Several patients reported balance issues and pain in other parts of their body (e.g., hips) that arose as a result of their offloading device causing a height differential of several inches between their feet:

"[…] the other offloading shoe, I didn't have a pair, I just had one shoe and so it threw off my back and my knees and my hips. So, it was very difficult because there was that height difference so you're already having a hard time, so then you're kind of, how do I put it? One side's higher than the other, so you're kind of hobbling along, and it does, it puts strain on the other parts of your body."

10.3.3.3.3 Sleeping

Several patients discussed challenges associated with sleeping with a TCC (Figure 14), which was described as sleeping with a *"10-pound weight on your leg."* One patient reported that the TCC ended up ripping their bed sheets while they were sleeping. Another patient described the TCC hitting their other leg during sleep, causing them to wake up

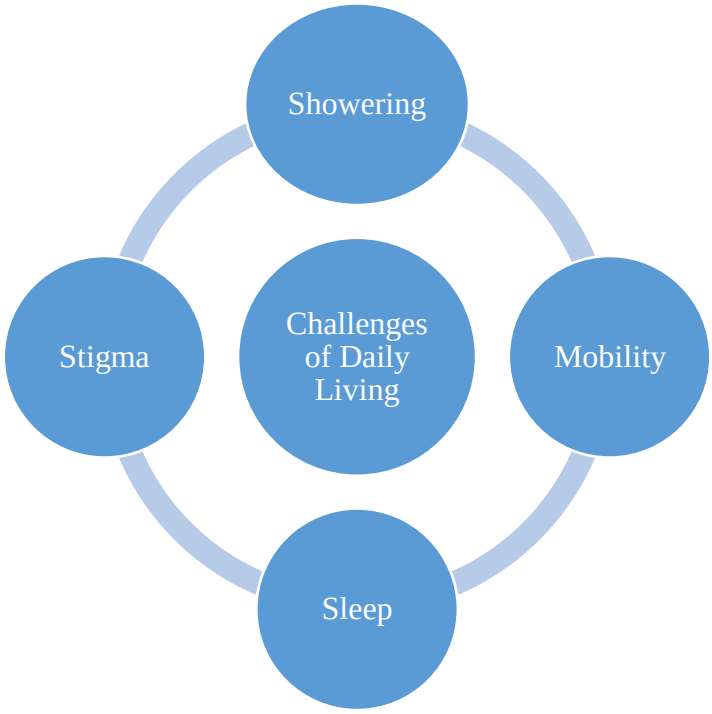
and to be afraid that the impact would cause another cut; the patient adjusted to this by wearing pajamas and socks and sleeping with a pillow between their legs.

10.3.3.3.4 Stigma

Several patients reported experiencing stigma, due to both offloading devices and amputations (Figure 14). One patient described drawing attention to themselves as a result of the clicking noise made by their offloading shoe. Another patient talked about the embarrassment associated with trying to put on the offloading boot in a parking lot. The difficulty of wearing sandals after having a DFU related toe amputation was described as follows:

> *"[…] if I'm wearing my offloading shoes, oh yeah, you know, you know I've got something wrong with me. If I'm just wearing running shoes, you can tell because my one foot and leg is more swollen than the other, but yeah, I mean, I used to wear sandal last year, so you could see that obviously, I'm missing a big toe. You can't really tell with the little one so much, but it's obvious the big toe's missing. But yeah, I mean, you can tell."*

Figure 15. Challenges with Daily Living with an Offloading Device



10.3.4 *Role of Patients and Their Support Network in Treatment*

Across interviews, patients generally reported following their health care provider recommendations for wearing offloading devices. However, several patients reported not wearing their maintenance offloading device after the DFU was healed, which was generally tied to them not realizing the effectiveness of the maintenance device and the likelihood of deterioration if they did not wear it. Among those who followed maintenance recommendations, the reasons for following them included education about the length of the healing process for their foot and being shown photos of the worst-case scenarios. One patient provided the following explanation given to them by their health care providers that encouraged them to wear their maintenance offloading device:

> *"I was like, "Oh, once it's healed, I can start walking again." And [the nurse] and my doctor go, "No, no, no, that's not how this works." I'm like, "What do you mean?" And they said, "This tissue is so fragile, and it could take a year to two years to build it up to the state where it was because of all the layers." So now is just wearing regular shoes for a very short period of time and putting pressure on that area is not to be done all the time if that makes sense. So, it's a graduated back to normalcy with my walking and pressure on it".*

Several patients reported that their health care provider showed them photos of how much deterioration they can experience if they do not wear their maintenance device, which served as motivation for them to wear it:

> *"Yes, so I put [the boot] on or I use my crutches. The reason why I am very careful about putting any weight on it without the boot on or anything is because [the nurse] showed me some pictures of people who did not go by... She says, "I always say, do not put your weight on it. Do not try and walk on it." She said, "This is what happens when you do." When she showed me, I was totally unaware that it could get that bad."*

However, other patients reported that they were told to wear their maintenance device, but did not think that this recommendation applied to short distances, such as wearing it around the house or to go to the bathroom at night, which led to re-ulceration:

> *"Because I was told that from the time I get up in the morning to the time I go to bed, I'd have to remember offloading my good shoes, the ones I wear now every day. I didn't want to do that. I would just be sitting in my chair, I'd get out and just throw a little pair of slip-ons on, go to the bathroom. I'm just going upstairs for dinner, whatever I just put it on, but these little slip-on things and I create purpose for myself. It bore the skin down on the back of my heel."*

Experiencing re-ulceration as a result of not wearing their offloading device as per provider recommendations was generally associated with self-blame and embarrassment: *"And then it reopened, I don't know how long after, because I was stupid and didn't wear my offloading special shoes all the time.*" Patients who had experienced re-ulceration as a result of not wearing their offloading device as recommended described it as a "learning experience" prompting them to wear the device in the future.

Most patients, particularly those who had a TCC on their right foot, described being reliant on their social supports to drive them to appointments. Social supports were also reported to help the patients with foot checks, changing dressings, and encouraging them to wear their offloading device. Several patients reported having very little social support. One patient described how their lack of social support affected their decision to not get a TCC, which was not a feasible option without having someone to drive them to the appointments.

10.3.5 *Life After a Diabetic Foot Ulcer*

10.3.5.1 Pain

Several patients described having residual pain after their DFU was healed. However, it was difficult to disentangle whether the pain was due to the offloading device, amputation, diabetes complications, other comorbid conditions, or combinations thereof. One patient described having considerable pain which they have to manage with Tylenol 3 and cannabis oil: *"It never goes*

away. The bone is trying to push through the bottom of the foot. It's awful." Another patient described the pain as *"[…] shooting pains up both legs."* A third patient talked about pain due to degeneration in the joints of their foot.

10.3.5.2 Ongoing Care and Maintenance

Some patients reported being acutely aware of what had caused their first DFU, such as stepping on a jagged rock, wearing a cast for another foot injury, or friction as a result of their daily work duties (e.g., truck driving). Other patients were unsure about what may have caused their DFU. Despite this, all patients reported accepting that they have to wear a maintenance offloading device for the rest of their life to prevent re-ulceration and to preserve their foot.

> *"I say to people, "My feet, I want to keep them, it's worth that." And I think too, I trust my doctors and [nurse] and the fact that they want the best for me, and I've always said as much as it pains me to pay that, at the end of the day, it helps my healing, which is what I am invested in is trying to heal as fast as I can. So, whatever's going to help that, whether it be going into the hospital every two weeks and getting debrided and it hurting like holy oh Jesus, then that's what you do. I said, "You guys have a job to do, I have a job to do."*

Patients who had experienced re-ulceration as a result of not wearing their maintenance offloading device reported having learned from that experience and being vigilant about prevention: "*Well, the biggest thing is for me is getting another cut. Right. I don't want another cut on my leg, so being a diabetic because you don't heal as fast as other people. So that was another learning curve*." Some patients were content having to wear these maintenance devices: "*Well if you figure I can offload this thing, the rest of my life I'm going to offload this. I'll buy more shoes and whatever*." Others expressed regret due to not being able to wear certain types of footwear: *"I'll never be able to wear a nice sandal again or a nice shoe. This is the only shoe that I have."*

Aside from having to continue wearing their maintenance offloading device, patients discussed the need for ongoing care, which included closely monitoring their foot and going in for regular

check-ups. The ongoing daily regimen for these patients was reported to include checking their foot for any visual symptoms (e.g., red lines), smells, and other issues. Patients also reported regularly seeing their offloading care provider who made adjustments to their maintenance offloading device as needed, including any customizations like additional foam or cut-outs.

10.3.6 *Suggestions for Change in BC*

10.3.6.1 Financial Support

Although many patients were able to get their offloading devices and treatment visits covered by their insurance provider, two patients living below the poverty line reported having to pay several thousands of dollars out-of-pocket to cover their treatment costs. Many patients generally expressed concern for others who may not be able to afford offloading, underscoring the often unexpected nature of DFUs: "*I'm just thinking, gosh, having to be out of pocket all the time for all these extra things that you're not planning on or counting on, it's hard.*" Several patients felt that treatment with offloading devices should be covered in BC.

10.3.6.2 Education

Several patients expressed the desire to have more education around what could happen if they do not wear their offloading device: "*A little more the explanatory of what really could happen. If you don't wear the shoe, this is what could progress into this or this."* Most patients also expressed the desire to have more information about which offloading treatments are available. Many noted that they were not aware of TCCs as a treatment option and endured several months of unsuccessful offloading treatments prior to getting a TCC. As one patient noted: "*The different treatments out there would have been the biggest thing. As well as information.*"

10.4 **Conclusions**

Interviews conducted with BC patients revealed that finding effective offloading care was a lengthy process, which was often characterized by months of ineffective treatments. During the time that the patients were not being properly offloaded, many had experienced infection of their DFU which necessitated several weeks or months of antibiotics; some reported watching the condition of their foot deteriorate. When patients did receive offloading care that helped to heal their DFUs, they reported being immensely grateful to their health care providers. This was

particularly evident in patients who had received TCCs and were able to observe their DFU healing very quickly after struggling to heal it for months. Although this varied across devices, patients generally reported that their offloading devices impacted their mobility, sleep, ability to shower, were associated with high cost and time-commitment (for appointments), and resulted in stigma. Despite the high cost of offloading treatment, which some patients had to pay out-of-pocket, most patients felt that it was worth it for them to save their foot.

Although most patients reported following treatment recommendations for wearing their offloading device for the initial healing of their DFU, some struggled to wear their maintenance devices, which led to re-ulceration. Some patients reported that their offloading care provider had explained how much their foot could deteriorate if they did not keep wearing the device, including showing them pictures; others reported wishing that they had received this information more explicitly. Most patients reported eventually accepting that they will have to wear their maintenance offloading device for the rest of their lives, despite it drawing attention to themselves and limiting their footwear choices. Broad suggestions for change that patients hope to see in BC included financial support for offloading treatment and education around the seriousness of the condition, options available, and what could happen if they do not wear the device.

Limitations of this patient interviews synthesis include the lack of data saturation and use of a convenience sampling strategy. Given that not all patient groups from all regions of BC could be interviewed, the experiences presented herein may not be reflective of all BC patients who have experience with offloading devices. The synthesis was generally consistent with the findings of a rapid review of patient perspectives conducted by CADTH (see Section 11).

11 Clinician Interviews

Summary

- From the interviewees' perspective, BC patients with diabetic foot ulcers are struggling to receive the right care, at the right time, and with the right provider.
- Cost was reported to be a major barrier to accessing care, with diabetic offloading devices and certain specialists (e.g., podiatrists) not publicly funded in BC.
- Many of the patients were reported to be "working poor" who cannot afford to take time off work to let their foot heal; as a result, recurrence rates are high.
- Diabetic foot ulcers were largely perceived to be a problem resulting from poverty rather than a health problem, with social determinants of health contributing to certain groups of patients being more vulnerable to this problem that others.
- Care providers across the province reported frustration with the lack of funding for their clinics, lack of access to a range of offloading devices, and lack of time to apply the devices and provide comprehensive care to their patients.
- There was considerable variation in the standard of care for diabetic foot ulcers across BC, with some clinics particularly under-resourced, while others have the funds to cover the cost of expensive devices (e.g., total contact casts).
- Interviewees stressed the importance of directing funding to preventative care.

11.1 Purpose

To understand the clinical experience with total contact casting, removable cast walkers, irremovable cast walkers, and other offloading devices for treatment of diabetic neuropathic plantar foot ulcers in British Columbia, including current practice, perceived benefits and drawbacks, clinical opinion on effectiveness, safety, societal impact and workforce implications, and considerations for the future.

11.2 Methods

11.2.1 *Data Collection*

Interviews were conducted by telephone with a purposive sample of clinicians. A snowball sampling approach was taken; clinicians initially identified by the BC Ministry of Health, and who agreed to be interviewed, were asked to identify other potential clinicians to contact. An effort was made to speak with clinicians from each health authority.

A semi-structured interview guide was developed; it was piloted with two clinicians and subsequently refined. This guide included questions on clinician experience with diabetic

offloading devices for treatment of diabetic neuropathic foot ulcers, perceived benefits and drawbacks of each technique; current clinical care pathways in BC; clinical opinion on safety, effectiveness, and workforce and societal impact; and future considerations for the use of diabetic offloading devices BC. The full interview guide can be found in Appendix E – Clinician Interview Guide.

11.2.2 *Analysis*

All interviews were conducted by an experienced, PhD-trained qualitative researcher, audio-recorded with the consent of the interview participants, and detailed notes were taken. The interviews were then transcribed for analysis.

The data were analyzed using the framework analysis methodology,[99,100] a form of qualitative content analysis, which is used to draw descriptive conclusions based on themes. Originally developed for policy research, this qualitative methodology is particularly useful for synthesizing data in order to support policy questions. Framework analysis involves categorizing data according to key issues and themes[100] and broadly involves seven stages: 1) transcription of the interviews; 2) familiarization with the interviews; 3) coding the interviews; 4) developing a working analytical framework; 5) applying the analytical framework to the existing categories and codes; 6) charting the data into the framework matrix; and 7) interpreting the data.[99]

After the interview transcription and familiarization processes were completed, the interviews were coded in QSR's International NVivo 12 qualitative data analysis software.[101] Data were coded by a single reviewer and verified by a second reviewer. Discrepancies between reviewers during this process were resolved through consensus. A working analytical framework that fit the interview data was developed and subsequently applied to the existing categories and charted in NVivo. Peer-debriefing was performed throughout all phases of the analysis process, following best-practice criteria set forth by Nowel et al. 2017.[102]

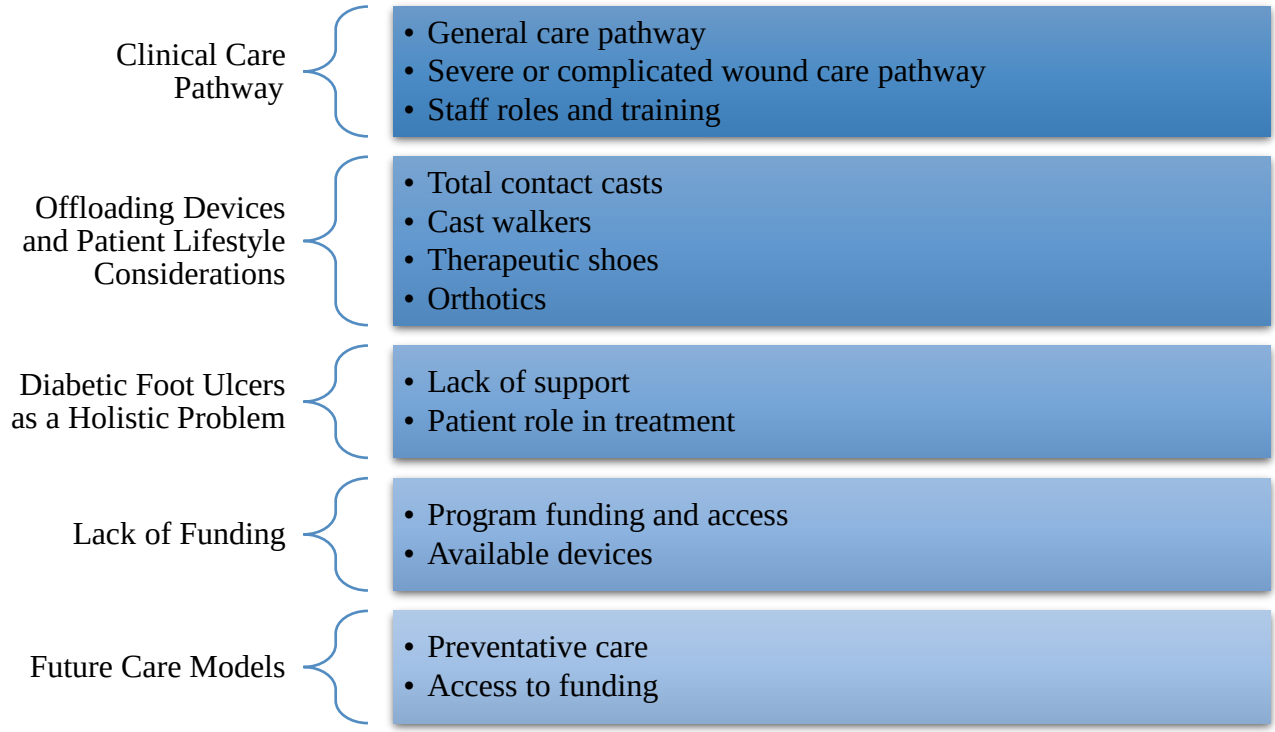
11.3 **Findings**

11.3.1 *Participants*

Telephone interviews were conducted in March – May 2020 with seven care providers (a podiatrist, an orthotist, a surgeon, and four nurses), all of whom have experience treating patients with diabetic neuropathic foot ulcers. The interviews ranged in length from 53 minutes to one hour and 23 minutes. Two care providers were from Vancouver Coastal Health, two from Fraser Health, one from Vancouver Island Health, one from Northern Health, and one from Interior Health. Of the seven care providers interviewed, four reported using TCCs, five reported using cast walkers, and six reported using other offloading devices (e.g., therapeutic shoes or orthotics, among others). The number of patients with DFUs seen ranged from 10-12 per month up to 30-35 per week. After the telephone interviews were completed, an additional care provider provided their feedback over e-mail. The care provider's responses validated the general themes discussed by the providers who were interviewed in-depth, further reinforcing that information saturation (redundancy) had been reached through the interview process.

The following six themes were identified in the analysis: clinical care pathway, offloading devices and lifestyle considerations, diabetic neuropathic foot ulcers as a holistic problem, impact of funding on treatment options, care coordination, and future care models (Figure 15).

Figure 16. Themes and Subthemes in BC Care Provider Interviews



11.3.2 *Clinical Care Pathway*

11.3.2.1 General Care Pathway

In a broad sense, care providers referred to two components of care for DFUs: healing and prevention. Healing starts with a referral from the patient's general practitioner (GP), community footcare or healthcare nursing, or by self-referral. Depending on the staffing mix in a clinic, patients might see a nurse for wound cleaning and debridement (i.e., removal of dead or infected tissue) and then see the clinic specialist (e.g., surgeon, podiatrist) for an assessment. The specialist may then decide to treat and offload the wound or may refer the patient to another specialist for wound care (e.g., orthotist) or to address infection or vascular issues prior to offloading. In clinics without a specialist, offloading might be performed by nurses who have varying training and resources at their disposal (e.g. some reported doing primarily TCCs, whereas others noted only having access to non-offloading devices, such as wound dressings).

> *"There's two parts of these diabetics' offloading. First part is the healing stage, what device are we using to offload during the healing process, and then once it*

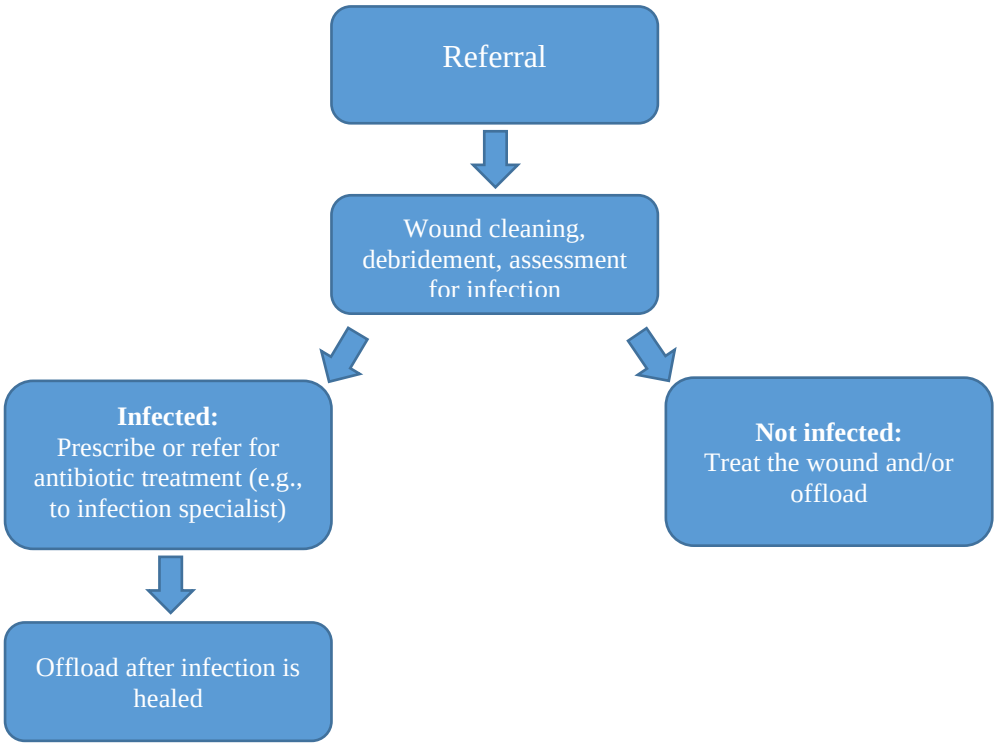
healed, what else we can put them on to prevent the wound from coming back. Otherwise, if you don't have the two pieces, you might as well not do the first piece. Because of what's going to come back right away."

Despite the substantial number of clinical care pathways that have been developed within Canada and globally (Section 6), interviewed care providers reported that within BC there is little standardization of care for treatment of DFUs, and no one care pathway is followed. Those interviewed had different preferences for DFU treatment based on experience and availability of supplies; yet, without a standard clinical care pathway, clinical preferences have led to inconsistencies in how DFUs are treated within BC. These differences appear to impact the types of offloading devices offered to patients, maintenance and follow-up after healing, and involvement of specialists differed across those interviewed. A general care pathway that emerged across interviews is reported in Figure 16.

Some care providers expressed frustration at this lack of standardization, noting that these inconsistencies can result in issues with healing and wound recurrences. For example, two care providers perceived that in some cases, patients with DFUs receive dressing changes only but are never offered support with offloading.

"I'd love to say there is a specific pathway, but there isn't…I'd like to say that debridement and a skin check is done every shift as per protocol, but they're not, and we know they're not being done. I'd like to say that everybody is getting a bed back and a skin check every day, but that's not the case. Workloads quite often don't commit that as well as the allocation of tasks varies, seems to be, from day to day."

Figure 17: General Care Pathway for Diabetic Foot Ulcers in BC



11.3.2.2 Severe or Complicated Wound Care Pathway

In contrast to the general care pathway, the treatment pathway for complicated wounds, such as for infections or arterial issues, was reported to be largely similar; although no care pathway was specifically mentioned (Figure 16). Care providers reported screening for signs of infection by taking the temperature of the patient's foot. In the event of an infection, care providers reported either prescribing oral antibiotics, referring the patient to their GP to prescribe oral antibiotics, or referring to an infection specialist for prescription of oral or intravenous antibiotics. It was noted that an infected DFU requires offloading; however, in most cases, a non-removable offloading device cannot be used until the infection is healed. Care providers also reported screening for vascular issues to determine whether there is adequate perfusion and offloading is appropriate. In the event of an arterial issue, providers refer to a vascular surgeon.

11.3.2.3 Staff Roles and Training

A variety of care providers were reported to treat DFUs in BC, including podiatrists, orthotists, physicians, surgeons, and nurses. The roles and responsibilities of the care providers interviewed

differed depending on the clinic and the resources available. Some clinics were reported to be multidisciplinary (e.g., staffed by an orthotist, nurses, and occupational therapists), whereas other clinics were reported to consist of individual care providers, such as a nurse or a podiatrist. In general, wound cleaning, debridement, and dressing were performed by nurses. Nurses also reported doing offloading, which ranged from advanced wound dressings to TCCs; nurse's roles depended on whether the clinic had a specialist and which resources were available. Diabetic foot care training among nurses was reported to range from training in advanced wound dressings to training as an NSWOC (nurse specialized in wound ostomy and continence). Nurses reported working closely with GPs and specialists for issues requiring referrals, surgeries, and prescriptions.

The role of a podiatrist was reported to center on offloading from a "mechanical perspective", as well as other treatments like nail care (Table 23): "*Our training is pretty heavily into biomechanics, the function of the foot, the function of the body. So, we really emphasize biomechanics, in terms of how ulcers form, and how they have to be treated*." Orthotists were reported to do pressure management and offloading, which included the design and modification of offloading devices. The role of a surgeon was reported to include wound assessment and performing minor surgical tasks (e.g., callus removal) prior to doing offloading. Lastly, the role of allied health professionals (e.g., physiotherapists) was reported to center on providing patients with additional support (e.g., gait assessment) during the treatment process alongside other health professionals.

Table 24. Staff Roles and Training for Treating Diabetic Foot Ulcers

Role	Responsibility	Training	Funding Model
Podiatrist	• Nail care • Some wound care • Offloading from a mechanical perspective (e.g., TCCs)	Doctor of Podiatric Medicine (DPM):[103] • Four-year undergraduate program in sciences; • Four-year program at an accredited College of Podiatric Medicine; • Comprehensive board and licensing exams; • One-to-three-year hospital-based residency program	Not covered by MSP ($23 covered for patients considered low-income)
Orthotist	• Offloading (e.g., TCCs) • Pressure management • If fitting the shoe, training the patient how to use it • Designing and modifying offloading devices	Certified Orthotist (CO):[104] • Undergraduate program; • Two-year accredited post-graduate orthotics and prosthetics program; • Two-year residency program under supervision of a CO; • Written and practical credentialing exam.	Not covered by MSP; sometimes covered by MPWD or Veterans Affairs
Nurse	• Cleaning, exposing, debriding, and dressing the wound • Offloading (range from wound dressing to TCCs)	Across interviews, ranged from specialized training in wound care to NSWOC designation. NSWOC:[105] • Registered Nurse (undergraduate degree, practice exam); • Graduation from a World Council of Enterostomal Therapists-recognized program.	Depends on the setting (covered by MSP if in a community clinic, not covered if in homecare or private clinic); some costs covered for PWDs or some Indigenous persons, depending on setting
Surgeon	• Assessing the wound • Minor surgery (e.g., removing big calluses) • Offloading (e.g., TCCs)	General Surgeon (GS):[106] • Undergraduate degree; • Medical degree; • Five-year residency program in general surgery; • Certification exam; • Additional training (length depending on specialty area).	Covered by MSP

Abbreviations: CO: Certified Orthotist; GS: General Surgeon; DPM: Doctor of Podiatric Medicine; Ministry of Persons with Disabilities; MSP: Medical Services Plan; NSWOC: Nurse Specialized in Wound Ostomy and Continence; PWD: Persons with Disabilities; TCC: total contact cast

Across the spectrum of roles, all care providers perceived wound care to be only one aspect of a very multifaceted disease that requires follow-up by other specialists: *"most diabetics, if they*

have a wound, they're being followed by someone else." There was a perceived discontinuity for treatment of DFUs, with multiple providers covering different aspects of wound care, such that patients may be receiving wound dressing changes from homecare, getting offloading for the wound from a podiatrist or an orthotist, and receiving diabetes education from a diabetes educator. One care provider characterized this discontinuity in care as resulting in treatment that is "fragmented":

> "*That's why so much of the treatments that you see in the community are fragmented because of who the heck can see a patient for an hour and a half? So it's very very few settings in healthcare where to change a dressing and to do some education you'd be able to dedicate that amount of time.*"

Thus, although care providers reported feeling that the ideal treatment approach to DFUs would be characterized by continuous and comprehensive care, the general sense across interviews was that they were unable to deliver this treatment to their patients due to a lack of resources, particularly time.

11.3.3 *Offloading Devices and Patient Lifestyle Considerations*

Care providers reported that they tailor which options they offer patients based on the patients' lifestyle and the options they have available (Table 24): *"They [patients] want the simplest thing that's not going to slow them down and they also want things that they're willing to wear."* Providers perceived TCCs to be the most effective device for healing DFUs, partly because they facilitate "forced compliance," since they cannot be removed without being cut off (see Section 10): *"A big part of the reason that total contact casting is so effective is because it's forced compliance."* TCCs were also described as expensive and associated with a considerable time commitment for the patient and the provider, requiring weekly cast changes and an application time of two hours. Many care providers expressed the desire to be able to use TCCs but an inability to use them due to resource constraints: *"I haven't used total contact casts. I'd like to use it and try it. But just the resource of accessing it, and the human resource of actually doing it is time consuming."* Providers also reported that TCCs are heavy and bulky; they affect the patients' balance and are difficult to walk in. As one care provider noted,

> *"From a patient perspective, it certainly creates some hardship for them. Because you're walking around with a cast…they have about an inch height difference [on one leg]. It's bulky. Yeah, it's just awkward for some people. But they do seem to recognize that it works.*

The provider added: *"Having no leg is also really awkward."*

The air boot was the most commonly discussed cast walker, which was reported to be perceived by patients as uncomfortable and causing balance issues, leading patients to not wear them: *"Most people, the aircast ends up sitting by the door. Nobody going to wear that thing at home, and that's often the problem is you walk into bathroom…you're walking to get food, you know, like that kind of stuff. Nobody going to sleep with it."* Care providers reported that therapeutic shoes (such as Darco shoes) may also create balance issues, requiring a step-to gait to be effective. It was also noted that therapeutic shoes may not fit the patient's foot or offload properly without tailoring:

> *"The problem with the generic shoes that you might be able to buy at the pharmacy or something is that they're not particularly ... They work for many patients, but they're not specifically personalized for a person's specific foot type or foot shape, so they're not specifically personalized for a given patient."*

Typically, Darco shoes were reported to be used on a short-term basis. Care providers noted that they would only use a therapeutic shoe if they were sure the patient would be able to wear it without causing more wounds.

Lastly, orthotics and therapeutic shoes were perceived as appropriate for preventing a wound, and for maintenance, once the wound is healed. However, providers noted that orthotics cannot be fitted over an open wound and need to be fitted properly in order to offload correctly.

Table 25. BC Providers' Perceptions of Different Offloading Devices

Device	Considerations (weight, falls, clinic visits)	Risks	Cost Estimates
Total Contact Cast	• Perceived as most effective • Resource intensive (time and money) • Unable to drive with right foot • Bulky and hard to walk in • Heavy (not appropriate for frail patients) • Cannot be fitted over an infected wound • Less risk of developing pressure in other areas	• Risk of falls • Unable to assess complications while cast is on	$1500-$3500 for cast, $100 per application
Cast Walker	• Perceived as uncomfortable • Easy to remove, which is conducive to patients taking off the device • Balance issues • Can cause pressure on other points of the leg	• Wound may develop or worsen if foot not monitored frequently	$165 for the boot, $80-$150 for the insole
Therapeutic Shoe	• Need to walk in step-to gait • balance issues due to 2-inch heel • Easy to put on • Looks like a regular shoe	• Generic shoe may not fit foot or offload correctly	$70 - $3000
Orthotic	• Cannot be fit over an open wound • If not selected properly, will not offload correctly	• Does not offload if not fitted correctly	$125 - $800

11.3.4 *Lack of Funding*

11.3.4.1 Program Funding and Access

Care providers expressed frustration with the lack of funding for diabetic foot care programs in BC. It was generally reported that programs were under-resourced, and some reported having their funding cut in recent years. As one care provider who reported having very limited access to offloading devices noted: *"We have best practice* [offloading devices] *for treating diabetic foot wounds but having access to the resource is our challenge. We know what to do, but we don't*

have the resource to do it." The demand for diabetic wound care was perceived to surpass the available services:

> *"I think the bottom line is funding. I think accessibility, you can always do better with that, but that comes down to funding. You can't offer more access if you don't have the funds to have more clinics. You can't have more patients being seen and followed without having more clinicians. Like our clinic, our diabetic wound clinic is packed. We can't see everybody we need to see."*

Care providers reported that access to diabetic wound care was generally challenging for patients financially, as well as geographically for patients living in rural/remote parts of BC. Notably, podiatry was reported to not be publicly funded in BC, with patients having to pay out-of-pocket. Patients living in Northern BC were reported to have very limited access to a podiatrist, as they come periodically from Vancouver to see patients and order them offloading devices not available in that clinic. It was also reported that some of the patients from a Northern Health private clinic go to Alberta to get TCCs because it is the closest location that offers TCCs and is reportedly covered in Alberta.

11.3.4.1 Available Devices

Care providers reported that offloading devices are not publicly funded in BC for most patients. Generally, it was reported that cast walkers, therapeutic shoes, and orthotics were covered for patients with Persons with Disabilities (PWD) designation and for some Indigenous peoples in certain settings. However, care providers noted that obtaining funding approval for these devices for these populations generally took several weeks; this was reported to be a barrier to providing the necessary care, given that DFUs frequently become more severe with each day they are not offloaded. The cost of TCCs was reported to be fully covered for all patients in one clinic; however, this was rare practice across BC due to differences in funding and/or institutional budgets across clinics.

Availability of offloading devices was reported to differ across clinics, and providers were generally frustrated by the constraints of not being able to offer patients the devices they deem to

be most effective: "*Right now, because I have no choice, [I offer] whatever I can get my hands on, whatever the client can get their hands on."* For instance, one care provider reported having access to TCCs that they could provide free-of-charge to their patients, whereas another provider reported only having access to felt to create a makeshift offloading device:

> *"It may be just them using a crutch or staying off of it. If they have a wheelchair, maybe spend more time in the wheelchair. I've also tried using cheap felt pads to sort of carve out the shape of the wound so that it takes a little bit of pressure off. Not ideal, but that's what I have, whatever I have from the toolbox."*

The challenge of limited access to devices was a frustration for the care providers, who also felt that treatment options were constrained by the barriers faced by low-income patients who were frequently unable to afford many of the offloading devices: "[Finding] *resources is the most challenging part of my job. I know what you need, but I can't get it for you, and you can't get it for yourself."*

11.3.5 *Diabetic Foot Ulcers as a Holistic Problem*

11.3.5.1 Lack of Support

Across care provider interviews, there was a sense that DFUs are a "poverty problem", underscoring how social determinants of health make some people more vulnerable to the development and worsening of this problem. Patients were often described as "working poor"; working multiple jobs often requiring them to be on their feet and unable to afford time off from their employment to let their DFUs heal. Also described as vulnerable to DFUs were pensioners and people living in shelters or on the streets. Another patient group facing challenges with offloading were those required to wear steel-toed boots at work or drive for a living; as a result, these patients are unable to wear certain types of offloading devices. As a result of not having the financial means to access offloading treatment for their DFUs, patients were reported to frequently experience recurrence and worsening of their ulcers, sometimes leading to amputation.

Providers perceived that patients with non-healing DFUs tend to lack social supports (e.g., patients either live alone or have few friends or family members): *"…frankly people who are*

well supported don't get these sorts of problems." Social supports were perceived as important for helping to remind patients to continue their offloading treatment; help them put on their offloading devices; check their feet in-between appointments (e.g., for redness, infection); help them manage their diabetes; and drive them to their appointments.

> *"The people we see with these chronic problems are poor, they're socio-economically disadvantaged, they either have no money or they have no support. In this context, is it really reasonable to ask them to stay off their feet if that affects their livelihood? Like if they're living from paycheck to paycheck and they have to work then how reasonable is it to say, "Well, you can't work"?*

11.3.5.2 Patient Role in Treatment

Patient compliance[1] was a theme that persisted throughout care provider interviews and was noted to be important contributing factors to the success of offloading devices: *"We can provide devices, we can give them nutritional information, our doctor can give a medication. But patient compliance is number one."* Compliance was reported to be low for offloading devices that can be taken off (e.g., cast walkers, therapeutic shoes, and orthotics), resulting in reduced effectiveness compared to non-removable devices: *"if they did what you asked all the time, for the most part, they would all heal."* However, despite their perceived effectiveness, non-removable devices were reported to be viewed by patients as uncomfortable for daily wear: *"If you put a cast on ... I had a guy who literally took a hacksaw to his cast. He said, I can't walk with this thing."*

Other factors affecting compliance from the care providers' perspective were obesity, denial, and social pressure. Some providers perceived obesity as a factor affecting compliance because it affects patients' ability to be able to get down to take off a removable offloading device or put it back on (e.g., an air boot) or check their foot regularly. Others noted that some patients are in denial about the risk and severity of DFUs and do not recognize the importance of wearing an

[1] "Compliance" was the term used by care providers throughout interviews to describe patient's role in treatment; we acknowledge that this term does not align with patient-centred language. It has been used here to be true to the content of the interviews.

offloading device, which is compounded by neuropathy due to diabetes: *"They don't feel the pain. If they actually feel the pain, then they might feel the extent of how it affects their lives, but because they don't feel, there's almost like no connection between my foot, and the rest of my body."* Lastly, providers perceived that their patients are not compliant because they do not want to stand out by wearing an offloading device: "*They don't want to stand out as having something wrong with them.*"

Care providers reported providing education to patients and their family members around issues surrounding their wound (e.g., how to change the dressing, checking the shoe daily for rocks) and the importance of offloading and treatment compliance: *"A lot of it is that the need for offloading, complete offloading, isn't well communicated, so I think some of it is an education and repetition issue."* The need for education in this patient population was emphasized: *"So part of it is the messaging. And part of it is you have to repeat that over and over and over and over every week."* One care provider reported feeling that some patient groups (e.g., immigrant communities, patients with mental health challenges) seem to struggle more with understanding the severity of DFUs and importance of treatment compliance. As a result, these particularly vulnerable groups may require additional resources around education and disease management.

11.3.6 *Future Care Models*

11.3.6.1 Preventative Care

Across interviews, care providers stressed the importance of preventative care for DFUs: *"I think a lot of time, we solve the problems then, here you go, then you come back when you have a new problem. We're not doing prevention."* There was a sense that the system is set-up to provide stop-gap solutions rather than preventative care:

> *"We spend billions and billions of dollars on illness care without actually promoting health, so again, that was a game changer in our clinic where initially we started off with patients that were chronic wound and we found that we couldn't do anything for most of them, and then we shifted our focus to can we identify relatively healthy patients to at-risk patients when they first get their wounds and then treat them, or even educate them before they get their wound. It's that emphasis on getting those high-risk*

patients earlier in their patient experience, so shifting from tertiary care to primary care and prevention. And believe me, that's such a difficult message to sell to executives right now because there's such a need for that end stage care, for hospitals and more surgeries and everything. And the idea that a smoking cessation program or a proper foot care plan where people actually look at their feet if their diabetic would be way more effective in the long term when there's the pressure from the public to actually provide all those services now."

11.3.6.2 Access to Funding

Care providers differed in their opinions of where the funding for diabetic wound care should be directed. Some felt that the funding should focus on specific offloading devices, whereas others suggested that the funding should be funneled into the entire treatment trajectory to prevent recurrence. As one provider noted: "*Sure, we can spend $3500 and put them in a total contact cast and get them all healed up in record time, but if you don't deal with the problem that caused the ulcer in the beginning, then they're going to have another ulcer."* Care providers advocating for increased funding for specific devices emphasized that the money should be directed to providers who have the appropriate scope of practice to dispense them, in order to ensure quality control: *"If you're going to just funnel the funnel money into devices, you'd better make sure that money is going to those... I'm being very careful how I word this… those practitioners who are trained to use them. Or at least provide some sort of educational process for people to gain that knowledge."*

11.4 **Conclusions**

Interviews conducted with BC care providers that treat DFUs revealed several barriers that are preventing patients from accessing the right care, at the right time, and with the right provider. Notably, it was reported that diabetic offloading devices are not publicly funded in BC and their out-of-pocket cost is prohibitive to many patients. Some care providers, such as podiatrists, are also not publicly funded, limiting accessibility to providers who specialize in foot care. In addition to not being able to afford the treatment for their DFUs, many patients were unable to take time off work to allow their foot to heal. This lack of access to devices, combined with the lack of access to maintenance treatment, was perceived to lead to high recurrence of DFUs.

Overall, care providers felt that DFUs are a “poverty problem” rather than a health problem, with patients experiencing poverty being more vulnerable to the development and worsening of this problem.

Other barriers preventing BC care providers from providing their patients with the care they need included the lack of funding for their clinics, lack of access to a range of offloading devices, and lack of time to apply the devices and provide comprehensive care to their patients. All these barriers led to a sense of frustration among providers, who felt they knew the appropriate treatment, but were unable to deliver it. There was considerable variability in the standard of care reported across the province. Some clinics were reported to be particularly under-resourced and forced to work with whatever little resources they had (e.g., using felt for offloading), whereas other clinics reported having the funds to cover expensive offloading devices (e.g., TCCs). Care providers differed in their opinions of where future funding for diabetic foot care in BC should be directed, but all stressed the need for funding focused on preventative care.

12 Cost – Utility Analysis

Summary

- This analysis compares cost and quality adjusted life year (QALY) outcomes between offloading options for the treatment of uninfected diabetic foot ulcers, from the perspective of the publicly funded healthcare system in British Columbia.
- The base case analysis used a decision tree to estimate the cost-utility of DFU treatments. ICWs are predicted to result in cost-savings with an incremental cost-effectiveness ratio (ICER) of -$132,295 when compared to no offloading treatment. The ICER for TCCs relative to no offloading treatment was -$119,151. The ICER for RCW relative to no offloading was dominated as it was found to offer less cost-savings and less QALYs than ICWs.
- Three-year and 5-year scenario analyses were considered using a Markov model. The conclusion from the longer time horizons were similar to the base case analysis where ICWs and TCCs offered cost-savings when compared to no offloading and RCWs were dominated by ICWs.
- This analysis suggests that ICWs and TCCs offer increased benefit and decreased costs for the treatment of uninfected DFUs.

12.1 Purpose

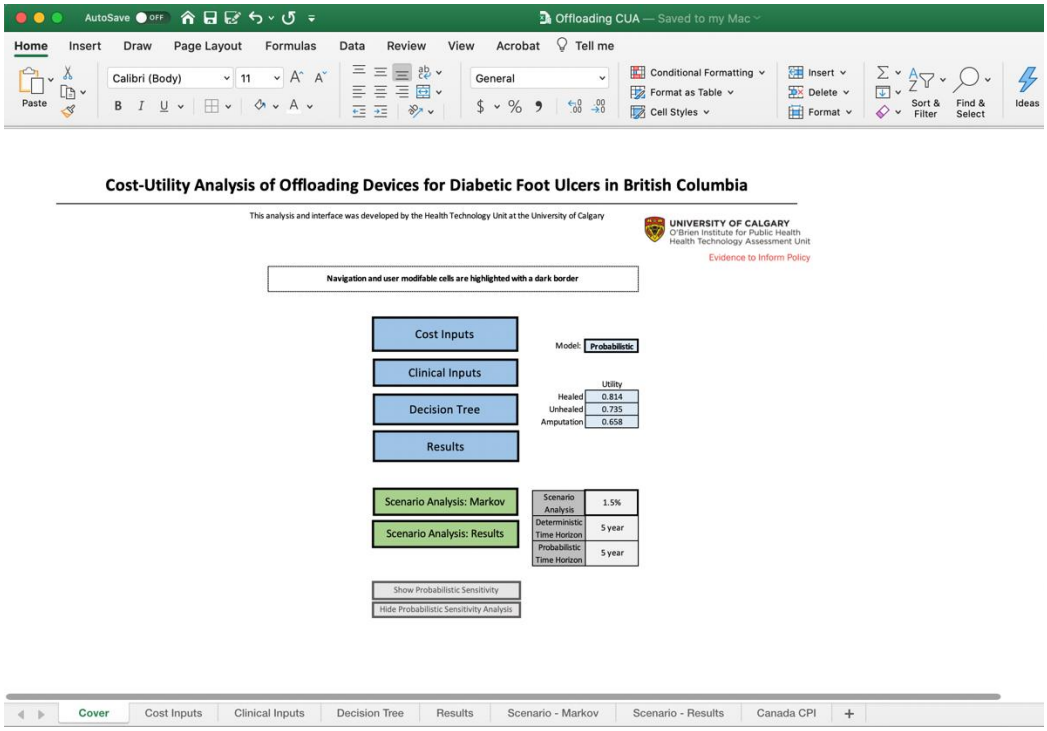
To estimate the cost-effectiveness of TCC, ICW, RCW, and no offloading for the treatment of uninfected DFUs from the perspective of a provincial publicly funded health care system. An Excel file entitled "Offloading CUA.xlsm" accompanies this work that allows the user to adjust model inputs as required (Figure 1). The base case analysis and all scenarios are adjustable through inputs on the "Cover" sheet, and the "Procedures and Costs" sheet.

12.2 Methods

12.2.1 *Model Overview*

The structure of the decision tree model is built using the previous health technology assessment by Health Quality Ontario as a guide.[107] Patients eligible for offloading devices are those with type I or II diabetes with a diagnosed uninfected diabetic foot ulcer without contraindications for offloading. Offloading devices considered included are TCC, ICW, and RCW; all three of which are currently available in British Columbia through private and public providers, although not publicly funded.

Figure 18. Cover page of "Offloading CUA.xlsx" user modifiable spreadsheet



For the base case, a decision tree was used for a 3-month time horizon (Figure 2). The treatment arms include all commonly used offloading devices as well as no offloading treatment, which was used as a reference case. The scenario analyses were conducted using a Markov model to evaluate a time horizon of 3 and 5 years using monthly cycles (Figure 3). The outputs from the decision tree and Markov models are calculated using probabilistic sensitivity analyses (PSA) with the option of displaying deterministic estimates.

Figure 19. Decision Tree

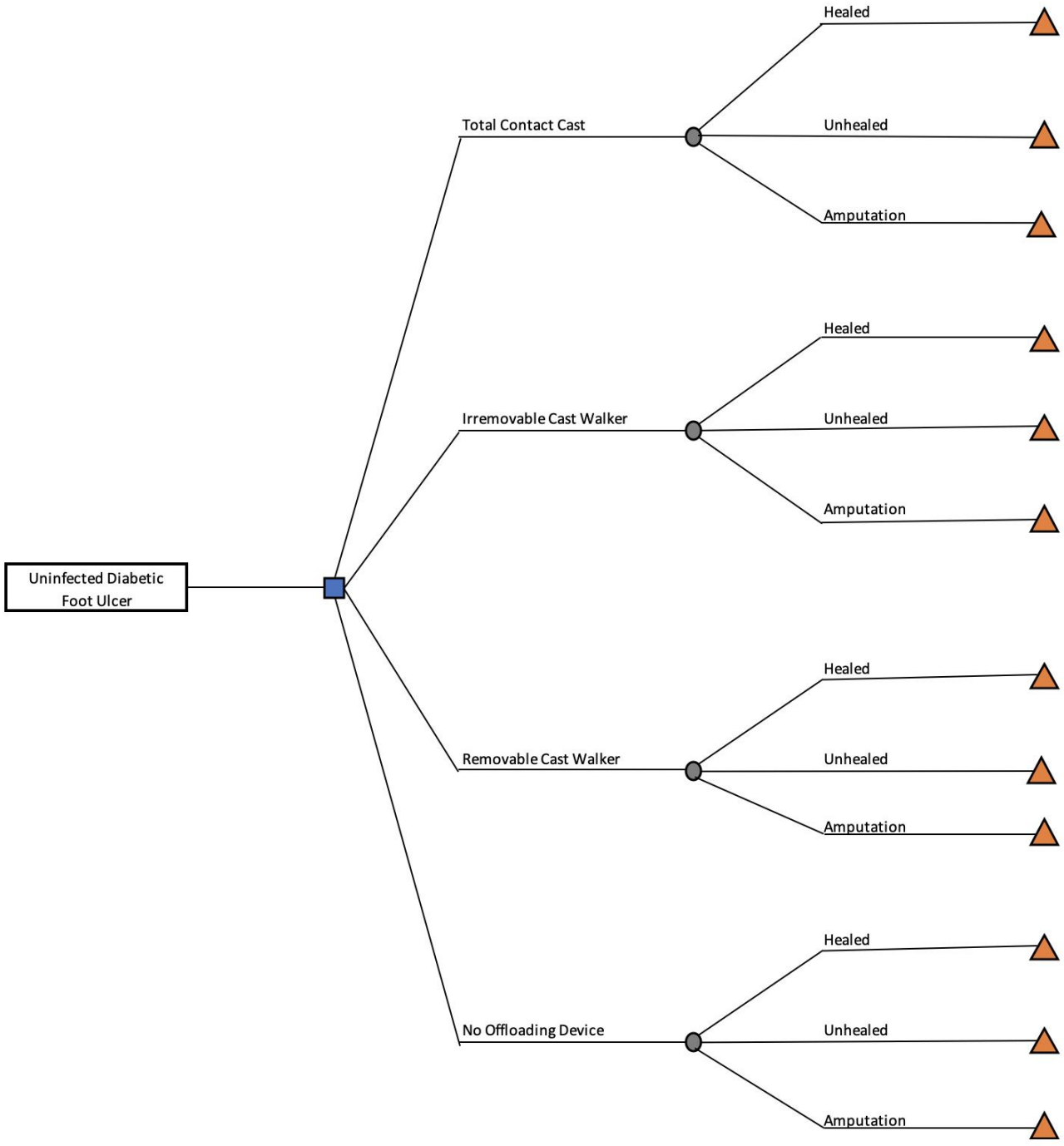
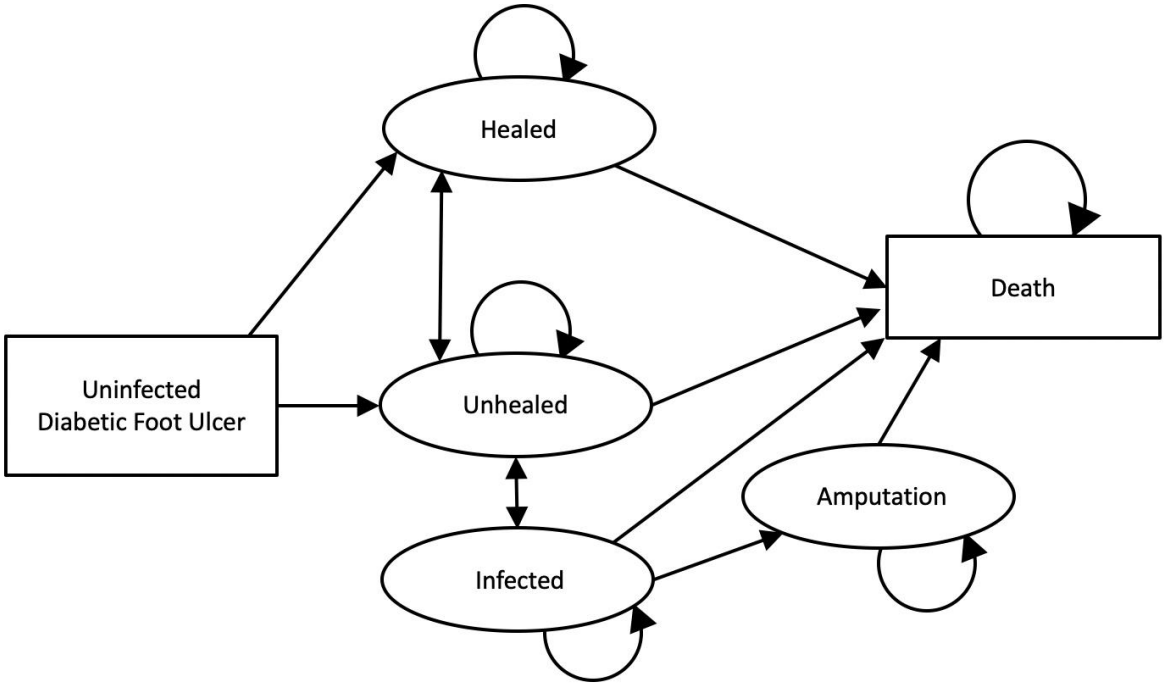


Figure 20. Markov model



The clinical effectiveness meta-analysis of RCTs was used to inform the clinical inputs for offloading devices in the model, including time-to-healing healing, proportion healed at 3 months, and probability of amputation. There is poor evidence of the effectiveness of not using offloading devices in the treatment of DFUs as there was a single RCT with a small sample found in the systematic review that was used to inform the inputs for the "no offloading" treatment arm.[92]

As the time horizon in the base case was 3 months, discount rate for costs and QALYs was not applied following the Canadian Agency for Drugs and Technologies in Health guidelines.[108] Cycle length of one week was applied with half-cycle correction. Where applicable, costs were

converted to Canadian dollars (CAD) with purchasing power parity, and adjusted to January 1, 2020 dollars with the Consumer Price Index for all items.[109]

12.2.2 *Probabilities*

Clinical inputs used in the analysis are shown in Table 25. The probability of healing and time-to-healing healing at 3 months are estimated though the meta-analysis completed as part of this HTA (Section 9). The probability of amputation at 3 months for offloading devices are the same as applied in the HQO report.[107] The probability of healing, time-to-healing healing, and probability of amputation for the treatment of diabetic foot ulcers without an offloading device are found from a single RCT with a small sample.[92]

Table 26. Clinical inputs

Description	Mean Value (SE)	Source
Time-to-Healing (Weeks)		
Total Contact Cast	5.3 (0.78)	Meta-Analysis
Irremovable Cast Walker	5.7 (0.40)	Meta-Analysis
Removable Cast Walker	6.2 (0.54)	Meta-Analysis
No Offloading	9.3 (1.69)	RCT
Probability of Healing at 3 months		
Total Contact Cast	0.83 (0.03)	Meta-Analysis
Irremovable Cast Walker	0.78 (0.05)	Meta-Analysis
Removable Cast Walker	0.71 (0.06)	Meta-Analysis
No Offloading	0.32 (0.11)	RCT
Probability of Amputation at 3 months		
Total Contact Cast	0.01 (0.03)	HQO
Irremovable Cast Walker	0.01 (0.05)	HQO
Removable Cast Walker	0.02 (0.06)	HQO
No Offloading	0.11 (0.11)	RCT

Using a Markov model, monthly transition probabilities between health states are used from Flack et al. (2008) for traditional treatment of diabetic foot ulcers (Table 26).[110] Health states included in the Markov model include healed, uninfected DFUs, infected DFUs, amputation, and death. Estimates of transition probabilities are not available for comparison between offloading

devices. Therefore, to meet the extended timeframes in scenario analysis it is assumed that patients transition between states based on their health state at 3-months following evidence from the base case analysis.

Table 27. Monthly transition probabilities between health states

		State at End of Cycle				
		Healed	**Unhealed**	**Infected**	**Amputation**	**Death**
State at Start of Cycle	**Healed**	0.960	0.031	–	–	0.009
	Unhealed	0.103	0.845	0.043	–	0.009
	Infected	–	0.082	0.872	0.038	0.009
	Amputation	–	–	–	0.880	0.120
	Death	–	–	–	–	1

12.2.3 *Cost*

Costs associated with offloading devices are based on administrative data from the British Columbia Ministry of Health, expert opinion from clinician interviews, and previously published research.[107,111] A summary of costs is shown in Table 27**.** Physician compensation for DFU services was estimated using administrative data of the British Columbia Medical Services Plan (MSP) claims of the average cost per DFU service. An annual increase of 0.5% for MSP costs under the 2019 Physician Master Agreement are included in cost estimates.[112] Wound care is assumed to be provided by a registered nurse. Estimates of nursing costs are obtained from the Provincial Collective Agreement between the Health Employers Association of BC and the Nurses' Bargaining Association.[113] Expert opinion from clinician interviews informed offloading device cost estimates. HQO estimates of costs of wound dressings and coban used in ICWs were used in the analysis.[107] Wound care for patients receiving no offloading treatment and RCW was assumed to occur every 3 days while the ulcer is unhealed. It is assumed that TCC and ICW patients receive weekly wound care when in the unhealed state, as found in practice guidelines and patient interviews.[114] Physician assessments are assumed to be performed bi-weekly during the unhealed state.[115] The treatment is assumed to continue during the mean time-to-healing.

Table 28. Cost estimates used in cost-utility analysis

Description	Cost	Source
Physician Compensation per DFU Service	$73.14	BC Administrative Data Physician Master Agreement
RN Compensation per Wound Care Service	$45.06	Provincial Collective Agreement
Dressing per application	$16.18	HQO
Coban Wrap per application	$26.97	HQO
Cast Walker	$165.00	Expert Opinion
Cast Walker Insole	$115.00	Expert Opinion
Total Contact Cast per application	$100.00	Expert Opinion
Physician Compensation per Amputation	$562.80	BC Administrative Data Physician Master Agreement
Hospital Cost per Amputation	$13,325.24	BC Administrative Data

12.2.4 *Utility*

Health-related quality of life utilities associated with health states are obtained from the estimates presented by Redekop et al. (2004).[116] In this study, the utility weights of different health states are calculated using a time trade off method. These results have been used in other economic evaluations of DFU treatments.[117,118] Redekop presented patient utility values for diabetic foot ulcers for various health states for healed, unhealed, and infected ulcers in patients with and without amputations. Also presented are utilities for various lower limb amputations, ranging from "1+ toes amputated", "one foot amputated", "one leg amputated", and "both feet or legs amputated." In this analysis the utility associated with the amputation state is estimated from the "one leg amputation" utility. The mean utility estimates and standard errors used are shown in Table 28. Quality-adjusted life years (QALYs) are calculated by summation of the estimated monthly utilities and then dividing the estimate by 12, equal to the mean monthly utility estimates over a year.

Table 29. Diabetic foot ulcer health state utilities used in scenario analyses

Health State	Mean Utility	Standard Error	Distribution	Source
Healed	0.84	0.0153	Beta	Redekop (2004)

Unhealed Uninfected	0.75	0.0204	Beta	
Unhealed Infected	0.70	0.0230	Beta	
Amputation Uninfected	0.63	0.0230	Beta	
Amputation Infected	0.59	0.0230	Beta	
Death	0	-	Fixed Value	-

12.2.5 *Monte Carlo Simulations*

To capture parameter uncertainty, model inputs were assigned distributions and allowed to vary independently in successive Monte Carlo simulations. Model convergence, less than 2% difference in cost and quality adjusted life year mean values, was realized with 1000 iterations. Healing probabilities and utilities are non-negative in this analysis and range from zero to one, therefore a beta distribution was assigned to these parameters. Both cost and time-to-healing are found to be positively skewed and non-negative, therefore a gamma distribution was applied. For offloading devices, the relative risk of healing of RCW and ICW compared to TCC was meta-analyzed using RCT data, for these instances a lognormal distribution was applied. The incremental cost-effectiveness ratio (ICER) 95% confidence intervals were calculated using the Fieller method in STATA 16.[119] Cost-effectiveness planes with 95% confidence ellipses were generated with R Statistical Software.[120]

12.2.6 *Scenario Analyses*

In the base case analysis, a time horizon of three months was considered using evidence from the clinical effectiveness meta-analysis and device-specific treatment costs. Scenario analyses were performed with a Markov model with a time horizon of 3 and 5 years. Health state probabilities over each time horizon are presented. All patients enter the Markov model following the 3 months of treatment from the base case analysis. If the DFU is unhealed the patient will remain on the treatment that was initially selected, providing an estimate of a longer time horizon using each treatment. Ray et al. (2005) found that the cost of treating infected DFUs are 2.1 times higher when compared to treatment of uninfected ulcers.[121] Costs associated with infected DFUs in scenario analysis were adjusted based on this finding. Infections are not considered in the base case analysis due to data limitations in the 3-month time horizon.

A 1.5% discount rate is applied to costs and QALYs in 3-and 5-year scenario analysis following CADTH guidelines.[108]

12.3 **Results**

12.3.1 *Validity*

This model relies on the published economic evaluations of the treatment of DFUs, including the 2017 offloading device HTA by HQO.[107] To assess internal validity, adjustments were made to model inputs and changes to model outputs in the expected direction and of the expected magnitude were evaluated. The Markov models used in scenario analyses were also validated. Estimates of the health state probabilities for TCC, ICW, RCW and no offloading treatment are shown in Figures 10-13. A high 5-year mortality was observed in all treatments, with 53.5%, 47.1%, 46.5%, and 44.9% of patients deceased with no offloading, RCW, ICW, and TCC treatment, respectively as shown in Appendix F – Cost-utility analysis health state probability estimates. This finding aligns with studies of DFU mortality.[122-124] In Markov analysis it was observed that there was a low proportion of patients in the amputation health state throughout the 5-year time horizon. The low amputation rate along with the high mortality supports the observation that patients have a high mortality once they move into the amputation health state.[110] External validity was not assessed, as there are no comparable models.

12.3.2 *Base Case Analysis*

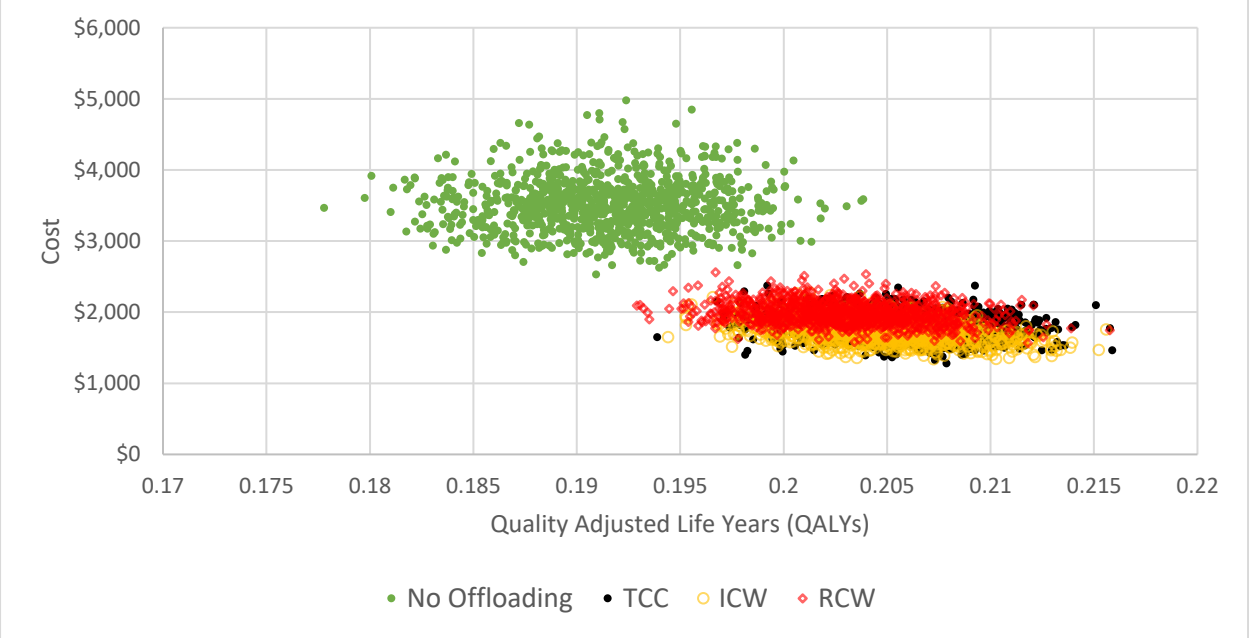
The base case analysis, using a time horizon of three months, found that the mean costs of no offloading treatment, RCW, ICW, and TCC were $3,526, $1,987, $1,737, and $1,775, respectively (Table 4). No offloading treatment was predicted to result in 0.191 QALYs, RCW was predicted to result in 0.203 QALYs, ICW was predicted to result in 0.205, and TCC was predicted to result in 0.206 QALYs. In all simulations, offloading devices resulted in decrease cost and increased QALYs for the care of diabetic foot ulcers compared to no offloading (Figure 20).

Table 30. Estimated QALYs and Costs by Diabetic Foot Ulcer Treatment at 3 months in Base Case Analysis

Treatment	Mean Cost (95% CI)	Mean QALYs (95% CI)	ICER (95% CI)
No Offloading	$3525.63 ($2774.93 to $4276.33)	0.191 (0.183 to 0.2)	-
TCC	$1775.35 ($1430.92 to $2119.77)	0.206 (0.199 to 0.213)	-$121,231.50 (-$120,249.76 to -$122,215.90
ICW	$1736.58 ($1418.51 to $2054.65)	0.205 (0.198 to 0.212)	-$134,243.51 (-$133,123.29 to -$135,366.99)
RCW	$1987.18 ($1668.17 to $2306.2)	0.203 (0.196 to 0.21)	-$132,234.21 (-$130,959.65 to -$133,513.29)

Abbreviations: CI: Confidence interval, ICER: Incremental cost-effectiveness ratio; ICW: Irremovable cast walker; QALY: Quality adjusted life year; RCW: Removable cast walker; TCC: Total contact cast

Figure 21. Estimated costs and QALYs of offloading treatments in base case analysis



The ICER when compared to no offloading was estimated at -$132,234 per QALY for RCW, -$134,244 per QALY for ICW, and -$121,232 per QALY for TCC as shown in Figures 21, 22, 23.

Figure 22. Incremental Cost and QALYs of (RCW) versus no offloading with 95% confidence ellipse.

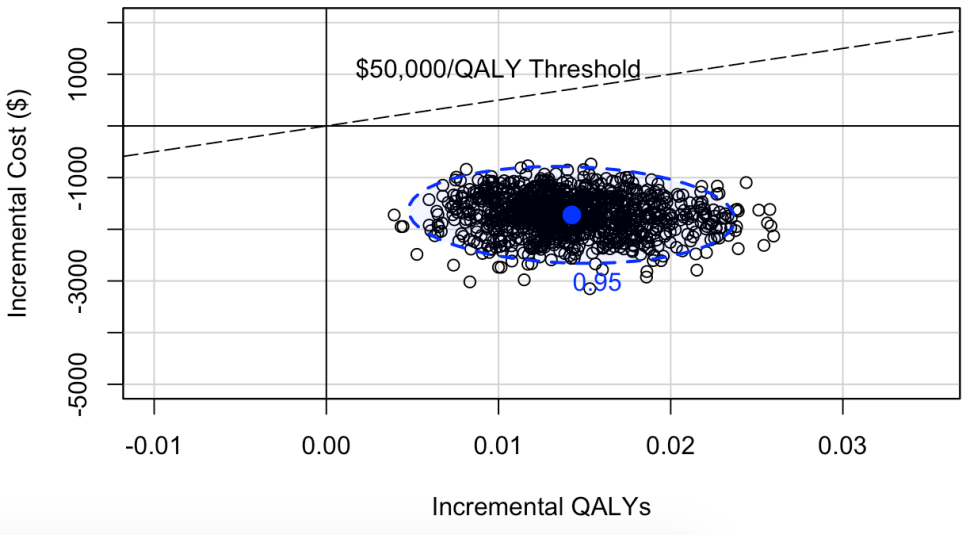


Figure 23. Incremental Cost and QALYs of (ICW) versus no offloading with 95% confidence ellipse.

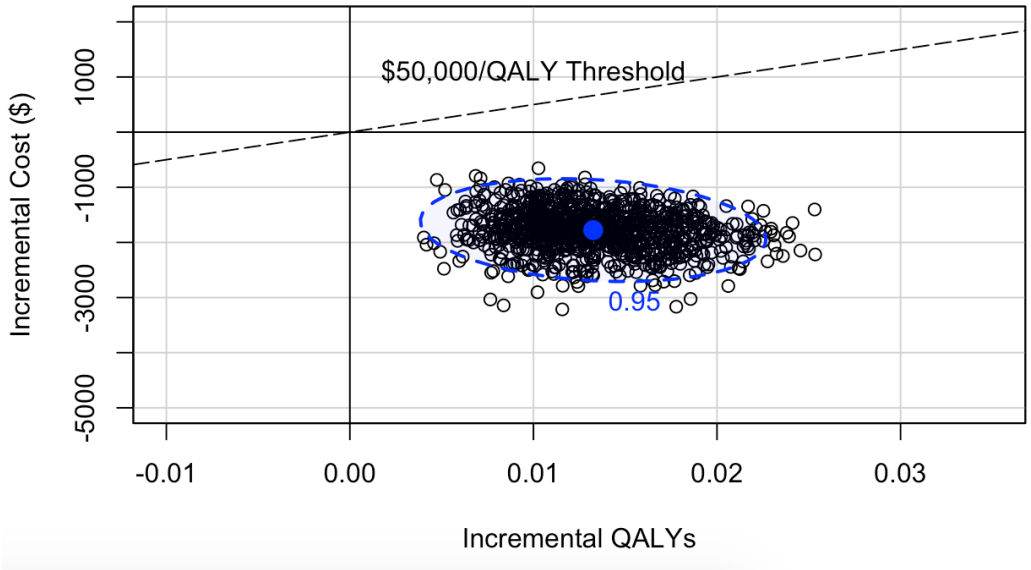
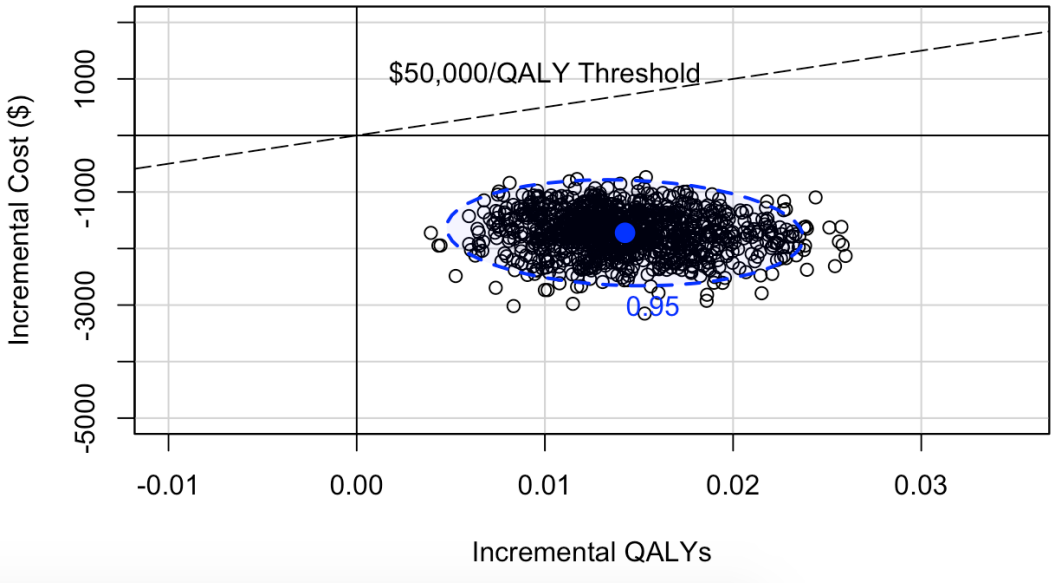


Figure 24. Incremental Cost and QALYs of (TCC) versus no offloading with 95% confidence ellipse.



12.3.3 *Scenario Analysis*

12.3.3.1 3-Year Time Horizon

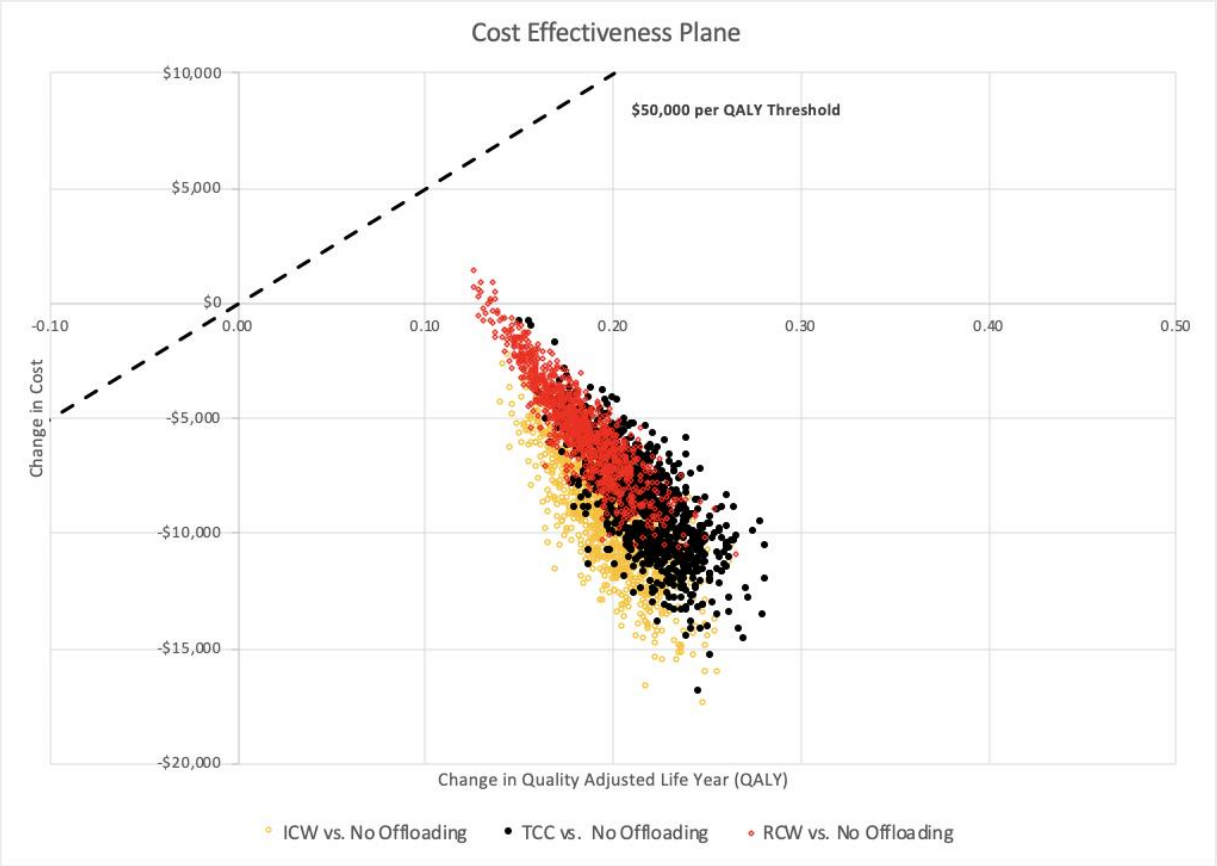
In the 3-year scenario analysis the mean cost of TCC, ICW, RCW, and no offloading were $13,171.29, $12,268.26, $16,427.95, and $21,946.97 respectively (Figure 21). TCC is estimated to result in 2.07 QALYs, ICW was estimated to result in 2.05 QALYs, RCW was estimated to result in 2.03 QALYs, and no offloading was predicted to result in 1.85 QALYs. Relative to no offloading, all offloading devices offered increased QALYs at decreased cost (Figure 24). The ICERs of treatment with offloading devices in comparison to no offloading treatment are -$40,244 for TCC, -$48,079 for ICW, and -$29,843 for RCW.

Table 31. Three-Year Time Horizon Scenario Analysis Outcomes

Treatment	Mean Cost (95% CI)	Mean QALYs (95% CI)	ICER (95% CI)
No Offloading	$21,946.97 ($17,533.32 to $26,360.61)	1.849 (1.791 to 1.907)	-
TCC	$13,171.29 ($12,107.67 to $14,234.91)	2.067 (2.008 to 2.127)	-$40,224.37 (-$39,738.41 to -$40,710.32)
ICW	$12,268.26 ($10,598.26 to $13,938.26)	2.050 (1.991 to 2.110)	-$48,079.17 (-$47,647.69 to -$48,510.62)
RCW	$16,427.95 ($13,646.28 to $19,209.61)	2.034 (1.976 to 2.095)	-$29,842.80 (-$29,563.56 to -$30,122.03)

Abbreviations: CI: Confidence interval, ICER: Incremental cost-effectiveness ratio; ICW: Irremovable cast walker; QALY: Quality adjusted life year; RCW: Removable cast walker; TCC: Total contact cast

Figure 25. Cost-effectiveness plane for comparison of TCC, ICW, and RCW to no offloading treatment in a 3-year time horizon.



12.3.3.2 5-year Time Horizon

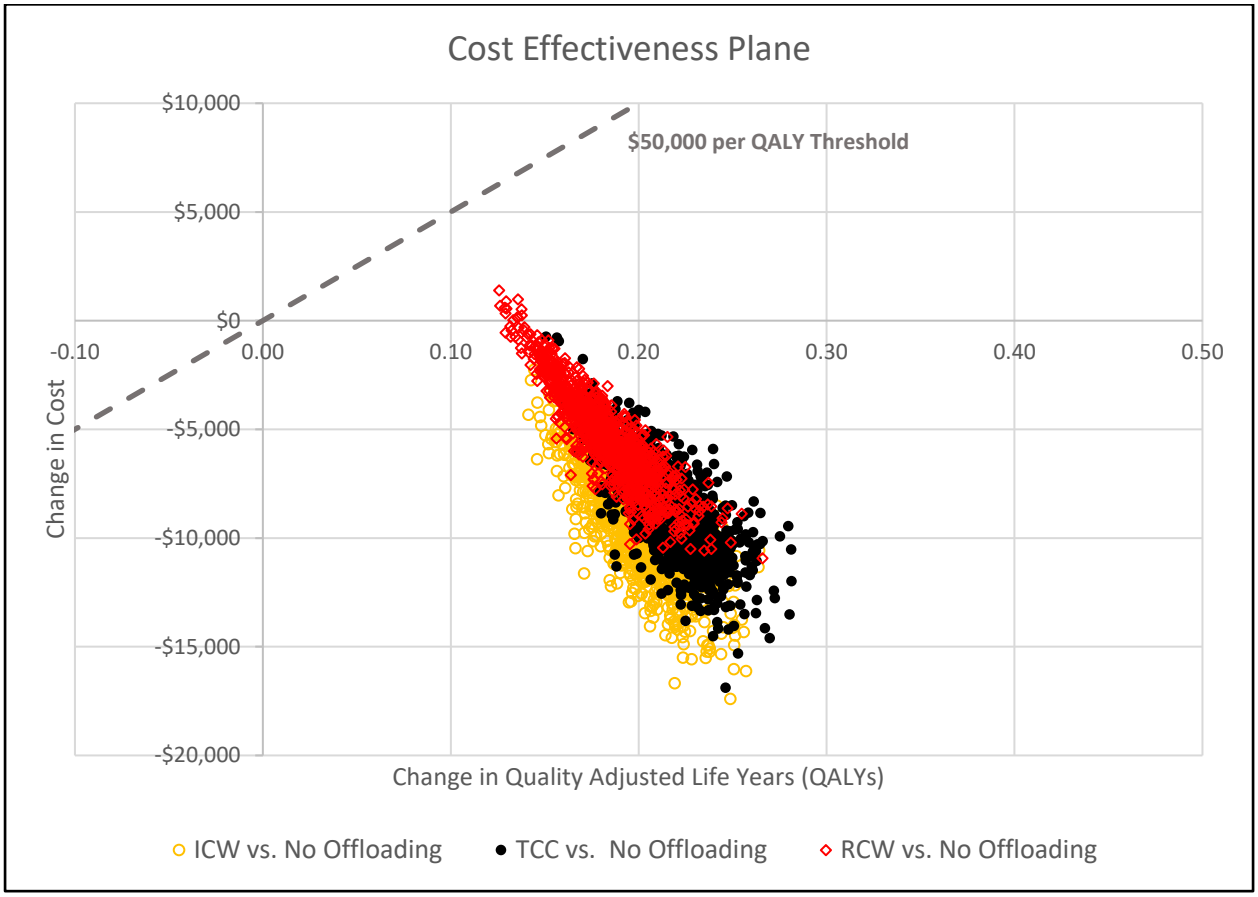
This scenario analysis extends the Markov model to a 5-year time horizon with the continuation of the monthly transition probabilities, costs, and utilities associated with each health state from the 3-year time horizon scenario analysis. As with other time horizons, offloading devices result in decreased costs and increased QALYs when compared to no offloading treatment (Figure 9). The mean cost of TCC, ICW, RCW and no offloading treatment strategies were $20,899, $18,907, $24,992 and $29,558, respectively (Table 31).

Table 32. Five-Year Time Horizon Scenario Analysis Outcomes

Treatment	Cost (95% CI)	QALYs (95% CI)	ICER (95% CI)
No Offloading	$29,557.98 ($24,733.08 to $34,382.88)	2.63 (2.54 to 2.72)	-
TCC	$20,898.66 ($19,739.05 to $22,058.28)	2.99 (2.9 to 3.08)	-$24,262.18 (-$23,937.24 to -$24,587.14)
ICW	$18,906.65 ($17,073.09 to $20,740.21)	2.95 (2.86 to 3.04)	-$33,610.25 (-$33,311.55 to -$33,908.92)
RCW	$24,991.86 ($21,434.95 to $28,548.78)	2.92 (2.83 to 3.01)	-$15,741.80 (-$15,603.48 to -$15,880.13)

Abbreviations: CI: Confidence interval, ICER: Incremental cost-effectiveness ratio; ICW: Irremovable cast walker; QALY: Quality adjusted life year; RCW: Removable cast walker; TCC: Total contact cast

Figure 26. Cost-effectiveness plane for comparison of TCC, ICW, and RCW to no offloading treatment in a 5-year time horizon



12.4 **Conclusions**

This analysis suggests that there are cost savings when offloading devices are funded by the public health provider in British Columbia. ICWs were found to have the highest cost-savings of

offloading devices with an ICER of -$134,243 per QALY when compared to no offloading treatment. When compared to ICWs, TCCs were found to have marginally higher QALYs (0.206 compared to 0.205) and a higher cost ($1775.35 compared to $1736.58) while having an ICER of -$121,232 per QALY when compared to no offloading treatment (Table 32).

The base case analysis was performed over a 3-month time horizon, while scenario analyses were performed over 3- and 5-year time horizons. A high 5-year mortality rate is estimated with all treatments, with moderately higher probability of mortality with no offloading treatment when compared to TCC and ICW. The probability of amputation over longer time horizons is comparable between devices.

The variation of costs between treatments is sensitive to the clinical effectiveness of offloading devices. The high frequency of dressing changes in the RCW and in no offloading treatment branches is the principle driver for increased treatment costs. Also contributing to the increased cost in RCW and no offloading is the increased time-to-heal and subsequent longer treatment time when compared to TCC and ICW. With a longer time-to-healing and lower proportion healed at 3 months, both RCW and no offloading treatments result in higher costs when compared to TCC and ICW.

The Health Quality of Ontario cost utility analysis assumed patients may switch devices if the DFU was unhealed at 3 months, and that they would not transition to other states for remaining 3 months in the 6-month time horizon. The evidence used this analysis was meta-analyzed from RCTs that observed outcomes at 3 months. The scenario analysis was able to incorporate infections and death over 3- and 5-year time horizons using monthly transition probabilities from a previous study.

This study had several limitations due to data limitations and necessary assumptions. In the base case, the 3-month time horizon uses data inputs from the systematic review of clinical effectiveness data and meta-analysis. Clinical outcomes available for meta-analysis comparing offloading devices were limited to time-to-healing and proportion of ulcers healed, evidence of long-term complications and outcomes is unavailable for offloading devices. Inconsistencies in

reporting prevented the inclusion of infection in meta-analysis and were unable to be included in the cost-utility analysis. Only one non-recent and small-sample RCT evaluated no offloading treatment in comparison to offloading.[92] While this study included outcomes of interest, the assumption that the findings are relevant today must be made cautiously.

A limitation of this study is the lack of device-specific health state transition probabilities. This model assumes that patients will move between health states over 3 and 5 years based on their outcome at 3 months. Ideally, transitions would be evaluated between devices and treatment modalities to improve the evaluation of the long-term outcomes associated with each treatment.

As with the HQO analysis, this study examined the treatment of a single DFU and does not consider the incidence of multiple DFUs that may occur during or the costs associated with repeat treatments following healing. Data were not available for recurrence between DFU treatments and as identified in clinician interviews, ulcer recurrence is frequent and may differ between treatments.

Table 33. Summary of Model Results with Mean Costs, Mean QALYs, and ICERs with 95% Confidence Intervals

Treatment	Outcome	Base-Case Analysis: 3-month Decision Tree	Scenario Analysis: 3-year Markov Model	Scenario Analysis: 5-year Markov Model
No Offloading	Cost	$3526 ($2775 to $4276)	$21,947 ($17,533 to $26,361)	$29,557.98 ($24,733 to $34,383)
	QALY	0.191 (0.183 to 0.2)	1.849 (1.791 to 1.907)	2.63 (2.54 to 2.72)
	ICER	–	**–**	**–**
Total Contact Cast	Cost	$1775 ($1431 to $2120)	$13,171 ($12,108 to $14,235)	$20,898.66 ($19,739 to $22,058)
	QALY	0.206 (0.199 to 0.213)	2.067 (2.008 to 2.127)	2.99 (2.9 to 3.08)
	ICER	**-$121,232 /QALY (-$120,250 to $122,216)**	**-$40,224.37 (-$39,738.41 to -$40,710.32)**	**-$24,262 /QALY (-$23,937 to -$24,587)**
Irremovable Cast Walker	Cost	$1737 ($1419 to $2055)	$12,268 ($10,598 to $13,938)	$18,906.65 ($17,073 to $20,740)
	QALY	0.205 (0.198 to 0.212)	2.050 (1.991 to 2.110)	2.95 (2.86 to 3.04)
	ICER	**-$134,244 /QALY (-$133,123 to -$135,367)**	**-$48,079 /QALY (-$47,648 to -$48,511)**	**-$33,610 /QALY (-$33,311.55 to -$33,909)**
Removable Cast Walker	Cost	$1987 ($1668 to $2306)	$16,428 ($13,646 to $19,210)	$24,991.86 ($21,434.95 to $28,548.78)
	QALY	0.203 (0.196 to 0.21)	2.034 (1.976 to 2.095)	2.92 (2.83 to 3.01)
	ICER	**Dominated**	**Dominated**	**Dominated**

Abbreviations: CI: confidence interval, ICER: incremental cost-effectiveness ratio, QALY: quality adjusted life-year

13 Implementation and Budget Impact Analysis

Summary

- Budget impact is predicted for three scenarios for the provision of offloading treatments for patients with DFU in BC: 1) status quo, 2) income-based funding of offloading treatments, and 3) age-based funding of offloading treatments. Treatments considered for funding are traditional dressings or no offloading (represents the status quo), RCW, ICW, and fiberglass TCC.
- All offloading treatments are predicted to result in cost savings relative to the status quo, with the magnitude of cost savings directly proportional to the number of patients for whom treatment is funded and likelihood of ulcer healing at 3 months.
- This analysis suggests that increased use of offloading treatments for patients with neuropathic DFU in BC is likely to result in cost savings for the province. Due to the lack of information on patients currently paying out-of-pocket for offloading treatment, cost savings may be overestimated, resulting in budget impact less favorable than this analysis suggests.

13.1 Purpose

To develop and consider implementation scenarios for the treatment of neuropathic diabetic foot ulcers with offloading treatments in BC, presenting relevant evidence for each, and to predict the comparative costs of each scenario to the publicly funded health care payer in BC over a 3-year time horizon. Offloading treatments considered in this analysis are traditional dressings or no offloading treatments, RCW, ICW, and fiberglass TCC.

13.2 Overview

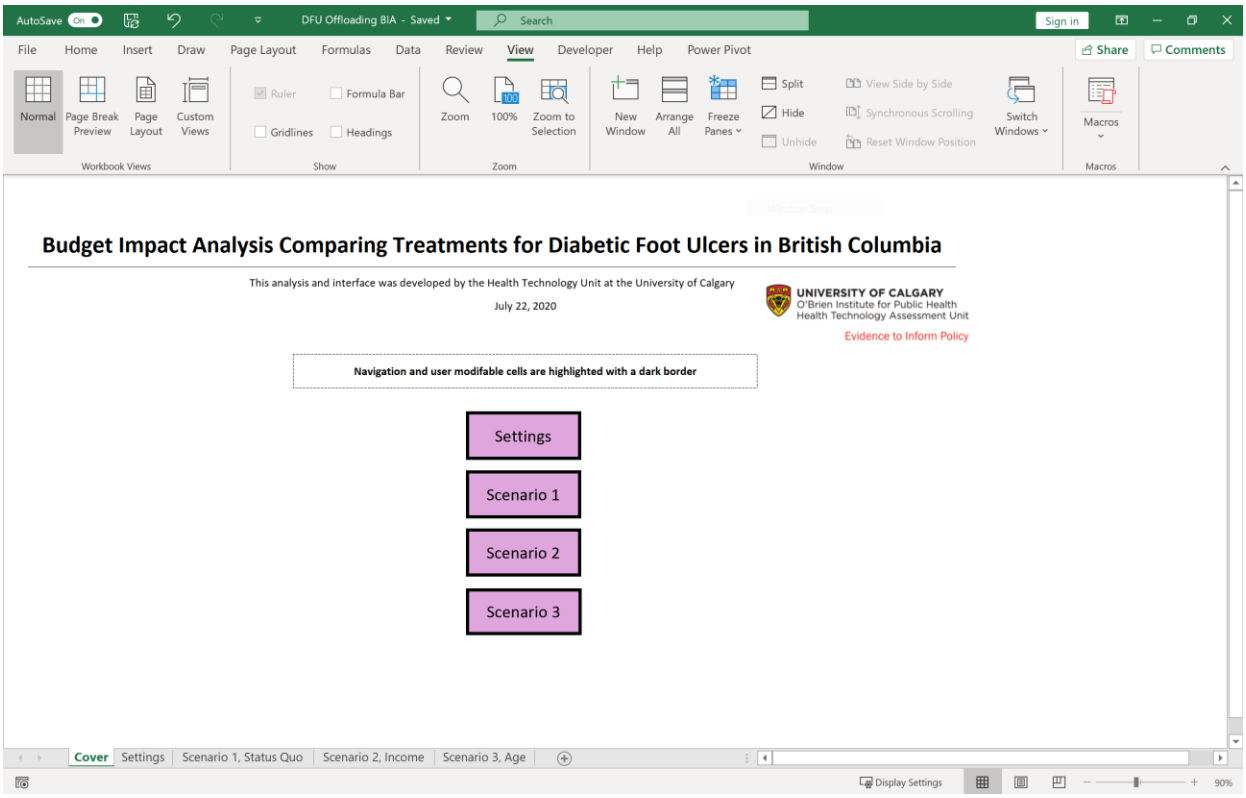
Based on the evidence reported herein, three implementation scenarios were developed for consideration: 1) status quo, 2) income-based funding of offloading treatments, and 3) age-based funding of offloading treatments. These scenarios were developed through an understanding of the BC context and current delivery patterns, and with consideration of the evidence presented within this HTA. This section presents the budget impact analysis, followed by the implementation considerations for each scenario.

13.3 Methods

A budget impact analysis was performed over a 3-year time horizon, corresponding to 2021, 2022, and 2023. Costs are considered from the perspective of the BC Ministry of Health and are

presented in January 2020 Canadian dollars. A user-modifiable Microsoft Excel spreadsheet is included with this report ("DFU Offloading BIA.xlsm"), allowing scenarios and strategies to be customized (Figure 26).

Figure 27. Budget Impact Analysis "DFU Offloading BIA.xlsm" Spreadsheet



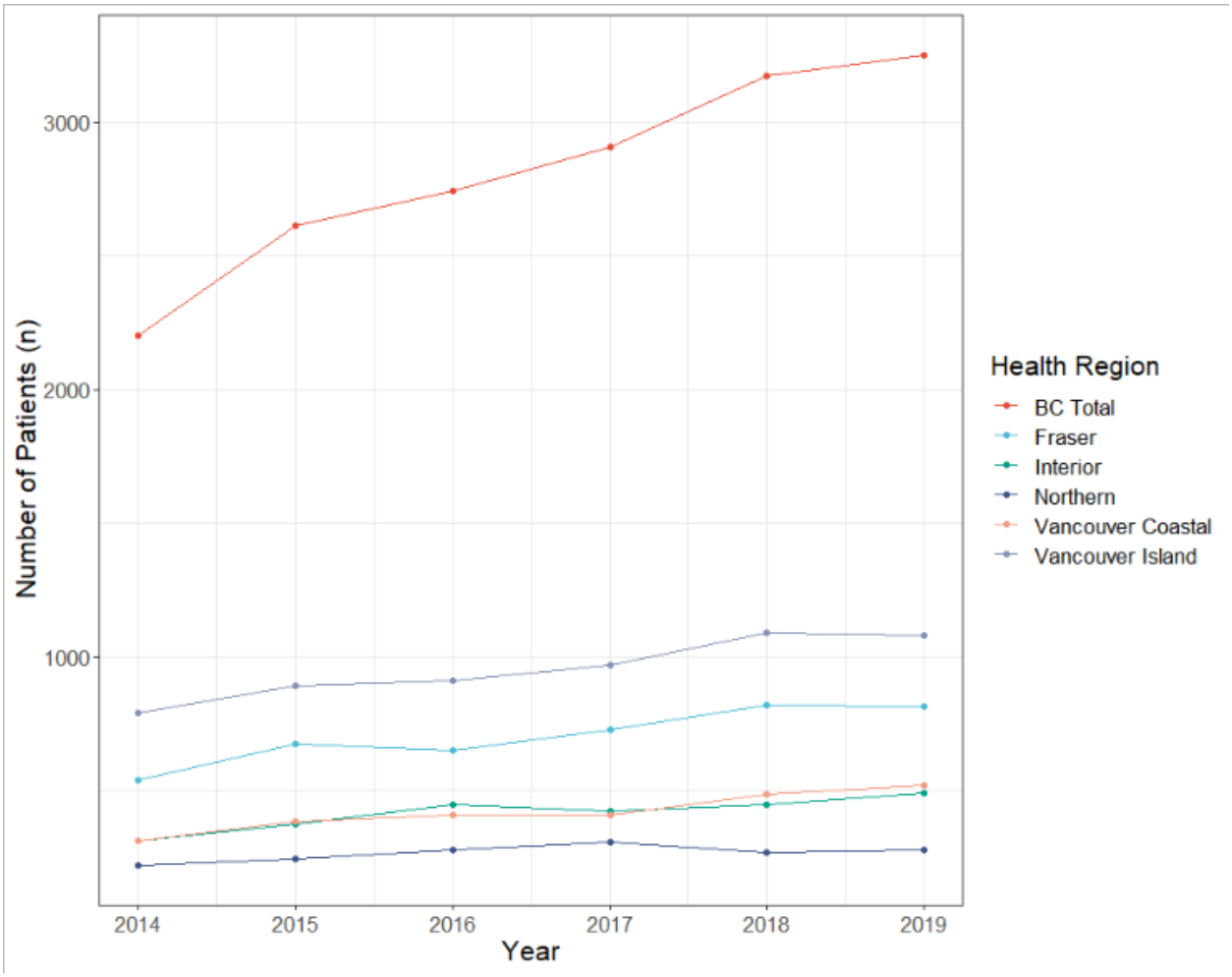
13.3.1 *Eligible Population*

The population of interest is patients with neuropathic diabetic foot ulcers (DFU), suitable for treatment with offloading treatments. To identify patients with diabetes, an administrative data case definition requiring two medical service plan claims for diabetes care within a year, or one hospitalization, captured in the discharge abstract database, was used. This case definition is commonly used by the British Columbia Ministry of Health.[125] From the cohort of patients with diabetes, patients with DFU were identified, using International Classification of Disease-10 CA (ICD-10CA) codes of E1^.70 (diabetes mellitus with foot ulcer) or E1^.71 (diabetes mellitus with foot ulcer with gangrene). This approach was also used by Hopkins et al. (2015) to estimate the economic burden of illness associated with diabetic foot ulcers in Canada.[126]

However, not all patients with neuropathic DFU are expected to benefit from offloading treatments. Prompers et al.[127] suggests that among patients with DFU, concomitant peripheral arterial disease, or lack thereof, should be defined as separate disease states. Peripheral arterial disease is a major underlying cause of ischemia and resulting DFU,[128] and a significant predictor of DFU non-healing.[127] In the systematic review of clinical effectiveness (Section 9), most trials excluded patients with peripheral arterial disease. To focus the case definition, ICD-10CA codes and Canadian Classification of Intervention codes representing exclusion criteria were selected in consultation with an expert clinician. These criteria were selected to identify the patient population with neuropathic DFU for which efficacy of offloading treatments is known. ICD-10CA codes used to identify patients with peripheral arterial disease, malignant, neoplasms, trauma, congenital deformities, or other conditions likely to affect efficacy of offloading treatment are listed in Appendix G – BIA codes used as exclusion criteria.

This resulted in 3,250 patients with neuropathic DFU eligible for offloading treatment in 2019 (Figure 27). From 2014 to 2019, the average annual change in the eligible population was 8.22%, thus, for this analysis, an eligible population growth rate of 8.22% was used. The user is encouraged to modify this value in the accompanying spreadsheet.

Figure 28. Patients with neuropathic DFU eligible for offloading treatments in BC Health Regions from 2014 to 2019. For patients with unknown health region, no line is shown but patients are included in total.



13.3.2 *Scenarios*

Three scenarios intended to show how the population might be divided, and resulting budget impact were considered: 1) status quo, 2) income-based funding of offloading treatments, and 3) age-based funding of offloading treatments. Offloading treatments considered in this analysis are traditional dressings or no offloading treatments, RCW, ICW, and fiberglass TCC. For the purposes of this analysis, the difference between RCW and ICW is the application of coban wrap applied to the RCW, making it irremovable. Since no data exists regarding the market share of

each device, no assumptions of relative market share were made. Treatments are considered individually, as if 100% of eligible patients were to receive the same offloading treatment.

13.3.2.1 Scenario 1: Status Quo

Within BC, offloading treatments for DFU are currently available through clinics where the patient pays for treatment out-of-pocket. However, the province provides wound care, represented by the traditional dressing or no offloading treatment, for neuropathic DFU. In the status quo scenario, costs to provide wound care only are considered. Since offloading treatments in BC are paid for by patients, no data are available to inform estimates of use; no assumptions regarding current use were made. In this scenario, no offloading is provided to patients with neuropathic DFU. To predict the budget impact of all other scenarios, total costs of the status quo are subtracted from the total costs of each scenario.

13.3.2.2 Scenario 2: Income Based Funding of Offloading Treatments

In this scenario, it is assumed that offloading treatments are covered by a program like Fair PharmaCare, with family deductible and family maximum specified by family income. On the Fair Pharmacare program, for families with net income between $28,750.01 and $30,000.00, the family deductible is $0.00.[129] Once the family deductible has been met, this program covers 70% of eligible costs until the family maximum of $800.00 is met.[129] Gross income stratified by amount is available for individuals only on the Statistics Canada website, which does not match the way that Fair Pharmacare deductibles and maximum are calculated.[130] Therefore, an alternate data source and simplifying assumptions were required.

In 2017, the median after-tax family income in British Columbia was $52,120.[131] One metric for understanding poverty is the low-income measure (LIM), which is calculated as the proportion of households living on less than half the median after-tax income, adjusted for family size. In 2016, 12.9% fell below the low income measure in British Columbia.[132] Given the small difference between the low-income measure cut-off for income of $ 26,060.00 in 2017 ($27,529.02 in 2020 CAD) and the cut-off for the family deductible at $30,000, it was assumed that 12.9% of individuals with neuropathic DFU eligible for offloading treatment fell into this category. The proportion of individuals categorized as low-income was assumed to be the same

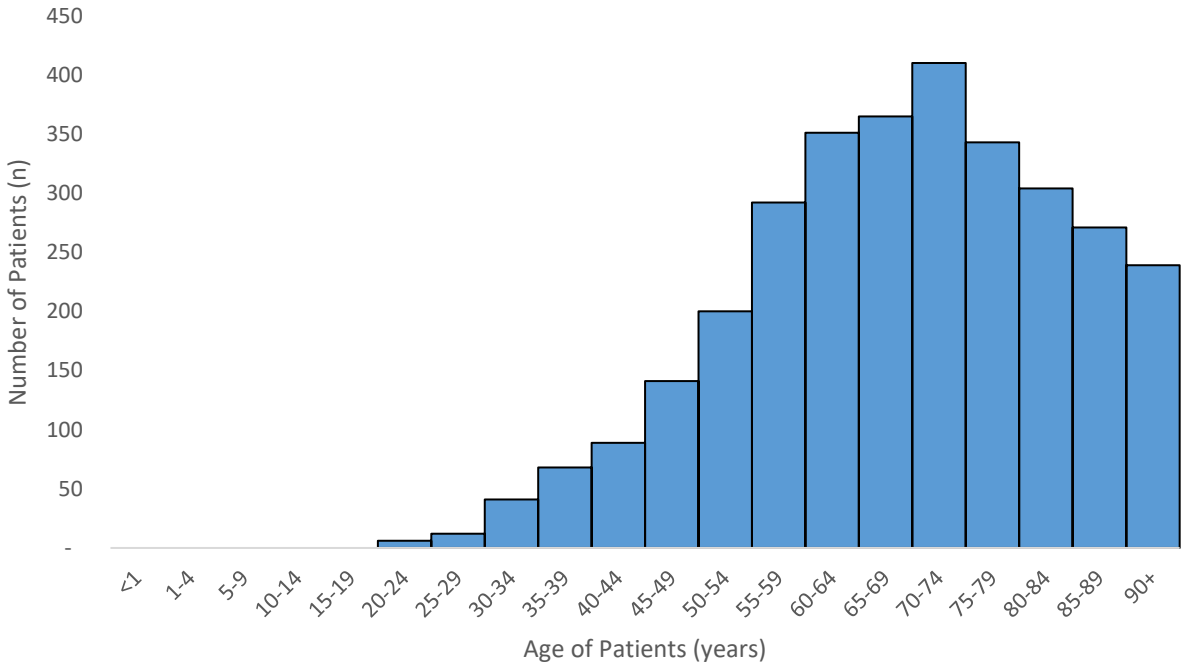
each year, and to have income of $30,000. For all individuals not classified as low income, it was assumed that their family income was equal to the median after-tax family income.

In 2017, the median after-tax family income (which is the most recent data available from Statistics Canada) was $52,120.00[131] – $55,058.04 in 2020 CAD. With this annual income, the family deductible on the Fair PharmaCare program is $1,700.00, and the family maximum is $2,275.00.[129] In the accompanying spreadsheet, options are provided for the user to specify the low-income cut-off and proportion with income below this value; and the same information for the remainder of the population. The spreadsheet calculates the family deductible and family maximum based on this information. Patients assume partial costs of offloading treatments depending on income, with the province continuing to assume all other costs of wound management that accompany offloading treatment.

13.3.2.3 Scenario 3: Age-based Funding of Offloading Treatments

In scenario 3, funding for offloading treatments is provided to eligible patients based on age. In British Columbia, most DFU patients eligible for offloading treatments are older patients, with mode between 70 and 74 years (Figure 28).[133] Patients with age 65 years or older are considered separately from patients with age below 65 years in this scenario; based on the observed distribution of neuropathic DFU by age. The user is encouraged to modify the age cut-off value in the accompanying spreadsheet.

Figure 29. Age distribution of DFU patients eligible for offloading treatment in British Columbia in 2019



13.3.3 *Costs*

This budget impact analysis has similar structure to that described by Health Quality Ontario.[107] Based on budget impact analysis best practice guidelines, no discounting is applied.[134] Use of results from the cost-effectiveness analysis described in Section 13 incorporates estimates of efficacy into resource use predictions; which is also congruent with best practice guidelines.[134]

Like the Health Quality Ontario budget impact analysis,[107] costs are split into device costs for the offloading treatments, and treatment costs, representing the wound care that accompanies offloading. For the traditional dressing treatment in which no offloading device is provided, device costs are zero. RCW and ICW incur the cost of cast walker and insole for all patients, which reflect expert opinion. Over the three months modeled in the cost-effectiveness analysis, all patients are assumed to incur device costs for the first three months of the year.

Treatment costs over the first three months, and the proportion of patients in unhealed health states are derived from the cost-effectiveness analysis (Table 33). Only those patients in the

unhealed health state at the end of month three were assumed to have ongoing dressing costs for wound management until the end of the year. These costs include bi-weekly physician assessment, dressing changes, and amputation; and were calculated as total costs from the cost-effectiveness analysis minus device costs. In this way, the user can adjust estimates of offloading device costs and corresponding budget impact predictions separately from wound management costs. After three months had elapsed, patients not in an unhealed health state were assumed to have no ongoing costs of DFU care. The patients ending in the unhealed health state at three months were assumed to continue to receive ongoing wound care provided by the province. These patients would not progress to receive amputation or move to the healed health state in months 4-12. Weekly physician assessments would continue for months 4-12, with dressing changes occurring every three days for all patients with unhealed ulcers.

Table 34. Budget impact analysis cost inputs

Treatment	Description	Value
Traditional dressing	Proportion unhealed at 3 months	0.57
	Device costs (months 1-3)	-
	Treatment costs (months 1-3)	$3,504.45
	Cost, months 4-12 • Dressing change unit cost: $61.24[107,113] • Dressing changes per month: 10.1 (every 3 days)[6] • Bi-weekly physician assessment: $74.90[125]	$7,024.32
RCW	Proportion unhealed at 3 months	0.27
	Device costs, months 1-3 • Removable Cast Walker: $165 • Cast Walker Insole: $115	$280
	Treatment costs, months 1-3	$1,697.95
	Cost, months 4-12 • Dressing change unit cost: $61.24[107,113] • Dressing changes per month: 10.1 (every 3 days)[6] • Bi-weekly physician assessment: $74.90[125]	$7,024.32
ICW	Proportion unhealed at 3 months	0.21
	Device costs, months 1-6 • Removable Cast Walker: $165 • Cast Walker Insole: $115 • Coban Wrap: $26.97/week[107]	$630.34
	Treatment costs, months 1-3	$1,145.23
	Cost, months 4-12 • Dressing change unit cost: $61.24[107,113] • Dressing changes per month: 10.1 (every 3 days)[6] • Bi-weekly physician assessment: $74.90[125]	$7,024.32
TCC	Proportion unhealed at 3 months	0.16
	Device costs, months 1-3 • TCC application: $100/week	$1299.00
	Treatment costs, months 1-3	$504.24
	Cost, months 4-12 • Dressing change unit cost: $61.24[107,113] • Dressing changes per month: 10.1 (every 3 days)[6] • Bi-weekly physician assessment: $74.90[125]	$7,024.32

Abbreviations: ICW: irremovable cast walker; RCW: removable cast walker; TCC: total contact casting

13.4 Results

13.4.1 *Scenario 1: Status Quo*

The predicted cost of maintaining the status quo (continuing to provide wound care and physician services, but no offloading treatments) over the next three years is $103,770,298.13 (Table 36). The predicted cost to the province per patient is $8,380.06 to provide traditional dressing treatment without offloading for neuropathic DFU; and the predicted change in budget impact is $0.

This scenario is not supported by the meta-analysis of the RCT literature, which found that TCCs, ICWs, and RCWs are all superior to no treatment without offloading with respect to time to healing; TCCs versus ICWs and TCCs versus RCWs are similar with respect to number of ulcers healed; and ICWs are superior to RCW with respect to number of ulcers healed (Table 35). This scenario also does not align with clinical guidelines recommending TCCs or ICWs as the standard of care for non-ischemic and non-infected wounds. Since availability and funding of offloading devices varies across BC clinics, access to offloading devices in this scenario would continue to be inequitable based on patients' geographic location.

This scenario does not align with perspectives of BC health care providers who advocate for funding of offloading devices and perspectives of BC patients who have experienced healing as a result of using an offloading device. The out-of-pocket cost of offloading devices (e.g., TCCs) was reported to be prohibitive for some patients, particularly low SES and other vulnerable populations. As a result, in this scenario, underserved populations would continue to have inequitable access to offloading devices.

The status quo scenario is characterized by several implementation considerations. Interviewed patients reported having little awareness of offloading treatment options available in BC (particularly TCCs) and wanting more information about all options available to them to avoid having to go through months of ineffective care; as a result, increased efforts to advertise these treatment options may be warranted. Interviewed BC patients and health care providers also reported a lack of funding for many foot care specialists in BC (e.g., podiatrists); as such, increased funding for foot care specialists in BC may need to be considered. Some patients

reported having very little social support which presents as a barrier to them accessing offloading treatment (e.g., needing someone to drive them to appointments); establishing transportation options for these patients or offsetting the cost of travel by public transit or taxi may facilitate improved access. Lastly, both the interviewed BC patients and health care providers expressed concerns about the medical advice regarding offloading treatments provided in the province; additional education around offloading treatments and devices available may be warranted for BC health care providers.

This scenario does not align with the cost-utility analysis, which suggests that allocating resources to offloading devices would provide health benefit and offer cost-savings. It also does not align with access to offloading devices in Ontario, Quebec, and Alberta, which offer various funding for different devices.

Table 35. Predicted budget impact over three years, by scenario and treatment. Negative budget impact (bolded) indicates cost savings.

Treatment	**Scenario 1:** Status Quo (n=12,383)	**Scenario 2:** Income Based Funding of Offloading Treatments		**Scenario 3:** Age-based Funding of Offloading Treatments	
		Low Income Patients (n=1,597)	Median Income Patients (n=10,786)	Above Age Cut-off of 65 years (n=6,188)	Below Age Cut-off of 65 years (n=6,195)
Traditional Dressing Treatment/No Offloading	Cost to Province: $93.4M Cost to Patients: $0 Predicted Budget Impact: $0	Cost to Province: $12.0M Cost to Patients: $0 Predicted Budget Impact: $0	Cost to Province: $81.3M Cost to Patients: $0 Predicted Budget Impact: $0	Cost to Province: $46.7M Cost to Patients: $0 Predicted Budget Impact: $0	Cost to Province: $46.7M Cost to Patients: $0 Predicted Budget Impact: $0
Removable Cast Walker		Cost to Province: $6.1M Cost to Patients: $0.1M Predicted Budget Impact: **-$5.9M**	Cost to Province: $39.0M Cost to Patients: $3.0M Predicted Budget Impact: **-$42.3M**	Cost to Province: $24.1M Cost to Patients: $0 Predicted Budget Impact: **-$22.5M**	Cost to Province: $24.2M Cost to Patients: $0 Predicted Budget Impact: **-$22.6M**
Irremovable Cast Walker		Cost to Province: $4.8M Cost to Patients: $0.3M Predicted Budget Impact: **-$7.2M**	Cost to Province: $27.8M Cost to Patients: $6.8M Predicted Budget Impact: **-$53.5M**	Cost to Province: $19.9M Cost to Patients: $0 Predicted Budget Impact: **-$26.8M**	Cost to Province: $19.9M Cost to Patients: $0 Predicted Budget Impact: **-$26.8M**
Fiberglass Total Contact Cast		Cost to Province: $4.1M Cost to Patients: $0.6M Predicted Budget Impact: **-$8.0M**	Cost to Province: $17.9M Cost to Patients: $14.0M Predicted Budget Impact: **-$63.5M**	Cost to Province: $18.3M Cost to Patients: $0 Predicted Budget Impact: **-$28.4M**	Cost to Province: $18.3M Cost to Patients: $0 Predicted Budget Impact: **-$28.4M**

Table 36. Implementation Considerations for Funding Offloading Devices in BC

	Status Quo (Scenario 1) *Continue to Not Fund Offloading Devices*	**Income-based Funding of Offloading Treatments (Scenario 2)**	**Age-based Funding of Offloading Treatments (Scenario 3)**
Condition Severity	• Diabetes is the leading cause of non-traumatic amputation in Canadian adults. • DFUs are common and serious diabetes-related complications arising from chronic hyperglycemia; while two thirds of ulcers heal, one third result in amputation due to infection. • In 2016 in BC, an estimated 5,000 to 8,300 patients had a DFU; approximately 1,000 of them required amputation.		
Health Benefits/Drawbacks	• Limited health benefits due to very few people being able to access offloading treatment. • Does not align with clinical guidelines that recommend TCC or ICW as the standard of care for non-ischemic and non-infected wounds. • Does not align with perspectives of interviewed BC health care providers and patients who advocate for funding of offloading devices.	• Meta-analysis found that TCCs, ICWs, and RCWs are similar with respect to time to healing; TCCs versus ICWs and TCCs versus RCWs are similar with respect to number of ulcers healed, but ICWs are superior to RCWs. • A review of HTAs found that TCCs or ICWs were likely to be the most clinically effective and cost-effective option. • Aligns with clinical guidelines that recommend TCC or ICW as the standard of care for non-ischemic and non-infected wounds. • Interviewed BC health care providers strongly advocated for funding of offloading clinics, including access to a range of offloading devices and additional time and resources to provide offloading care. • Interviewed BC patients who used TCCs reported observing quicker healing compared to other offloading devices they have tried before; patients who did not use TCCs reported varying degrees of healing.	
Non-Health Benefits/Drawbacks	• Limited non-health benefits due to very few people being able to access offloading treatment.	• Many of the interviewed BC patients reported that they were unable to work as a result of their DFU; having access to timely, effective offloading treatment may help patients return back to work.	
Ethical Considerations	• Patients would continue to have limited access to offloading treatment. • Does not align with funding for offloading devices in Ontario, Quebec, and Alberta, which offer various funding for different devices.	• Patients would have increased access to offloading treatment. • Would partly align with funding for offloading devices in Ontario, Quebec, and Alberta, which offer various funding for different devices.	
Underserved Populations	• Current access to offloading treatment is inequitable across the province; access to devices varies by clinic. • The out-of-pocket cost of offloading treatment (particularly TCCs) is prohibitive to some patients, particularly to low SES and other vulnerable populations.	• Access to different offloading devices may continue to vary across BC clinics, as accessibility appears to be tied to clinic funding in general.	• Access to different offloading devices may continue to vary across BC clinics, as accessibility appears to be tied to clinic funding in general.

	Status Quo (Scenario 1) *Continue to Not Fund Offloading Devices*	**Income-based Funding of Offloading Treatments (Scenario 2)**	**Age-based Funding of Offloading Treatments (Scenario 3)**
	• In this scenario, underserved populations would continue to have inequitable access to offloading devices.	• Interviewed BC patients who lived below the poverty line reported not having insurance coverage and struggling to afford the out-of-pocket cost of offloading devices (several thousands of dollars); income-based funding would allow these marginalized groups to access offloading treatment.	• Age-based funding may restrict access to offloading treatment for those outside of the funded age group.
Evidence of Cost-Effectiveness	• This scenario does not align with the cost-utility analysis, which suggests that allocating resources to offloading devices would provide health benefit and offer cost-savings.	• These scenarios align with the cost-utility analysis, which suggests that ICWs and TCCs offer increased benefit and decreased costs for the treatment of uninfected DFUs. Resources allocated to ICWs and TCCs are predicted to have a greater health benefit than other treatments and offer a cost-savings.	
Environmental Impact	• Unknown environmental impact. Considerations may include driving distance to the offloading treatment centre, and the environmental impact of manufacturing, and disposing of, offloading devices (particularly TCCs).		
Implementation Considerations	• Interviewed BC patients reported having little awareness of the existence and availability of certain offloading devices (mostly TCCs). Patients reported wanting more information about all options available to avoid having to go through months of ineffective care; increased efforts to advertise these treatment options may be warranted. • Some interviewed BC patients reported having very little social support which presents as a barrier to accessing offloading treatment (e.g., needing someone to drive them to appointments); establishing transportation options for these patients or offsetting the cost of travel by public transit or taxi may facilitate improved access. • Interviewed BC patients and health care providers reported a lack of funding for many foot care specialists in BC (e.g., podiatrists); increased funding for foot care specialists in BC may need to be considered.		
Risk Registry: Financial	• The estimated budget impact of maintaining the status quo (continuing to provide wound care and physician services, but no offloading treatments) is $0. The predicted cost to the province of maintaining the status quo over the next three years is $93,384,274.71,	• The estimated budget impact of income-based funding for offloading devices in comparison to the status quo varies from $0 to a savings of $63.5M. The predicted cost to the province over three years varies from $4.0M to $81.3M.	• The estimated budget impact of funding TCCs based on age in comparison to the status quo varies from $0 to a savings of $28.4M. The predicted cost to the province over three years varies from $18.3M to $46.7M.

	Status Quo (Scenario 1) *Continue to Not Fund Offloading Devices*	**Income-based Funding of Offloading Treatments (Scenario 2)**	**Age-based Funding of Offloading Treatments (Scenario 3)**
Risk Registry: Human Resources	• Some interviewed BC patients reported receiving medical advice regarding offloading treatment that led to deterioration of their condition. Some interviewed BC health care providers also expressed concerned about offloading treatments being administered by providers who may not have the necessary training. As such, additional education around offloading treatments and devices available may be warranted for BC health care providers.	• Increased access to offloading devices may be associated with increased demand for treatment. Interviewed BC health care providers report that current clinic resources are already very strained; therefore, increased demand would require recruitment, training, and funding of additional human resources (e.g., nurses, podiatrists, surgeons, orthotists) for primary healing and maintenance treatment of DFUs. • Some interviewed BC patients reported receiving medical advice regarding offloading treatment that led to deterioration of their condition. Some interviewed BC health care providers also expressed concerned about offloading treatments being administered by providers who may not have the necessary training. As such, additional education around offloading treatments and devices available may be warranted for BC health care providers.	

Abbreviations: BC: British Columbia; DFU: diabetic foot ulcers; ICW: irremovable cast walker; RCW: removable cast walker; SES: socioeconomic status; TCC: total contact casting

13.4.2 *Scenario 2: Income Based Funding of Offloading Treatments*

In this scenario, low-income patients with income of $30,000 per year have a deductible of $0 and family maximum of $800; median income patients with income of $55,058 per year have a deductible of $1,700 and family maximum of $2,275. In Figure 29, predicted budget impact by treatment for the number of patients in the low income and median income groups is shown. This figure demonstrates that the greater the number of patients receiving offloading treatments, the greater the cost savings. For the province to achieve the greatest cost savings possible of $71,423,037 relative to the status quo, all patients wound need to receive fiberglass total contact casts (Table 36). Costs to the province in this case would be $21,961,236, and costs to patients would be $14,633,365.

This scenario is supported by the meta-analysis of the RCT literature, which found that TCCs, ICWs, and RCWs are similar with respect to time to healing; TCCs versus ICWs and TCCs versus RCWs are similar with respect to number of ulcers healed; and ICWs are superior to RCW with respect to number of ulcers healed. This scenario also aligns with clinical guidelines recommending TCCs or ICWs as the standard of care for non-ischemic and non-infected wounds.

This scenario aligns with perspectives of BC health care providers who advocate for funding of offloading devices and perspectives of BC patients who have experienced healing as a result of using an offloading device. Many of the interviewed BC patients reported that they were unable to work as a result of their DFU; having access to timely, effective offloading treatment may help patients return back to work. The out-of-pocket cost of offloading devices (e.g., TCCs) was reported to be prohibitive for some patients, particularly low SES and other vulnerable populations. As a result, income-based funding would allow these marginalized populations to access offloading treatment. However, although in this scenario patients would have increased access to offloading treatment, availability of offloading devices may still vary across BC clinics, as accessibility appears to be tied to clinic funding in general.

The income-based funding scenario is characterized by several implementation considerations. Interviewed patients reported having little awareness of offloading treatment options available in

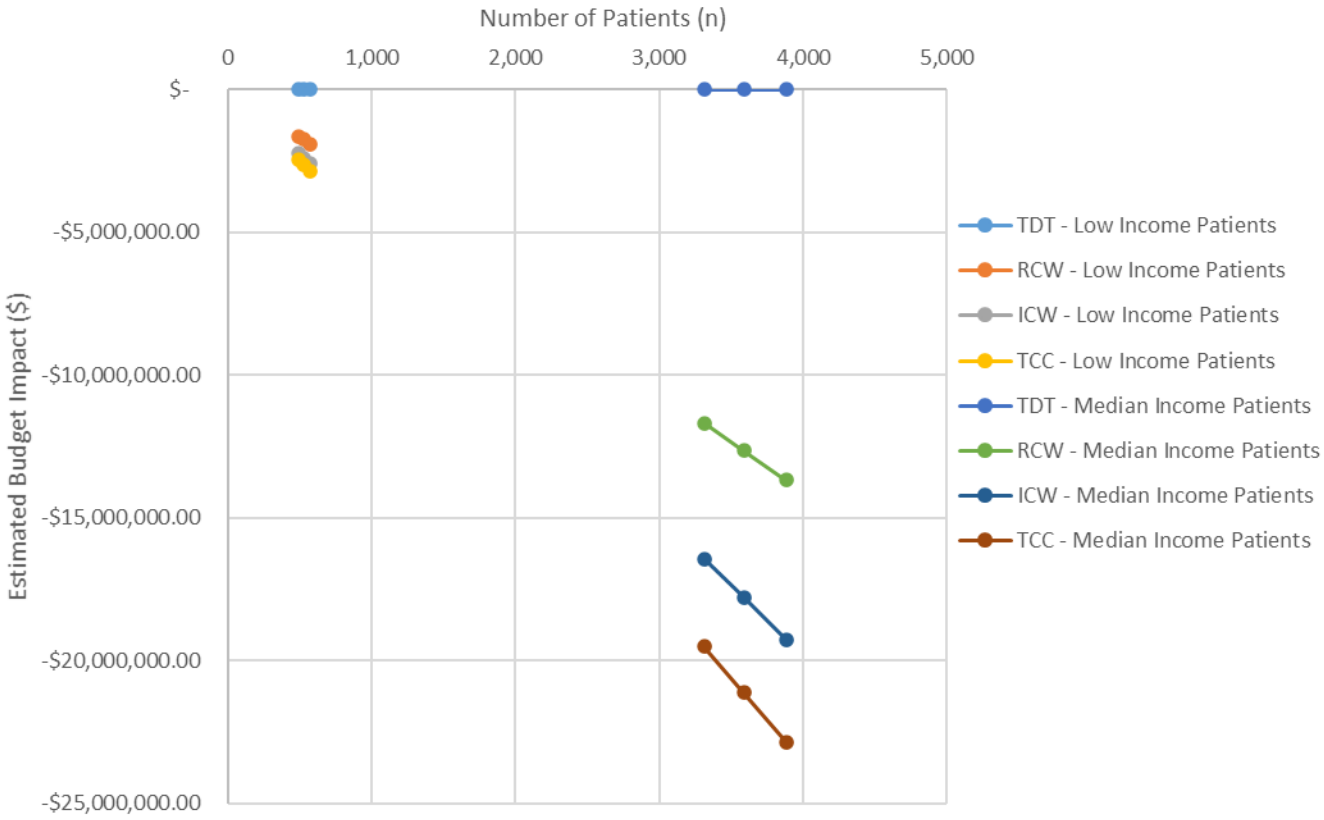
BC (particularly TCCs) and wanting more information about all options available to them to avoid having to go through months of ineffective care; as a result, increased efforts to advertise these treatment options may be warranted. Interviewed BC patients and health care providers also reported a lack of funding for many foot care specialists in BC (e.g., podiatrists); as such, increased funding for foot care specialists in BC may need to be considered. Some patients reported having very little social support which presents as a barrier to them accessing offloading treatment (e.g., needing someone to drive them to appointments); establishing transportation options for these patients or offsetting the cost of travel by public transit or taxi may facilitate improved access. Lastly, both the interviewed BC patients and health care providers expressed concerns about the medical advice regarding offloading treatments provided in the province; additional education around offloading treatments and devices available may be warranted for BC health care providers.

This scenario aligns with the cost-utility analysis, which suggests that ICWs and TCCs offer increased benefit and decreased costs for the treatment of uninfected DFUs. Resources allocated to ICWs and TCCs are predicted to have a greater health benefit than other treatments and offer a cost-savings. It also aligns with access to offloading devices in Ontario, Quebec, and Alberta, which offer various funding for different devices.

Table 37. Predicted budget impact for low income, median income, and all patients, by treatment. Assumes 100% coverage with each treatment.

Patients	Treatment	Year 1	Year 2	Year 3	Total
Low income patients (total n=1,597)	Traditional dressing treatment	$0	$0	$0	$0
	Removable cast walker	-$1,829,922	-$1,978,999	-$2,142,984	-$5,951,905
	Irremovable cast walker	-$2,218,676	-$2,399,424	-$2,598,246	-$7,216,346
	Fiberglass total contact cast	-$2,443,118	-$2,642,150	-$2,861,085	-$7,946,352
Median income patients (total n=10,786)	Traditional dressing treatment	$0	$0	$0	$0
	Removable cast walker	-$13,004,509	-$14,075,468	-$15,232,732	-$42,312,709
	Irremovable cast walker	-$16,442,158	-$17,796,218	-$19,259,397	-$53,497,773
	Fiberglass total contact cast	-$19,509,106	-$21,115,738	-$22,851,842	-$63,476,686
All patients (total n=12,383)	Traditional dressing treatment	$0	$0	$0	$0
	Removable cast walker	-$14,834,431	-$16,054,467	-$17,375,716	-$48,264,614
	Irremovable cast walker	-$18,660,834	-$20,195,642	-$21,857,643	-$60,714,119
	Fiberglass total contact cast	-$21,952,223	-$23,757,888	-$25,712,927	-$71,423,038

Figure 30. Predicted budget impact to provide offloading treatments to low income and median income patients, by treatment.



13.4.3 *Scenario 3: Age-based Funding of Offloading Treatments*

In this scenario, costs for persons above age 65 were considered separately from persons below age 65, which resulted in 50% of eligible patients in each category. Without the requirement that patients contribute towards cost of their offloading treatment, there was no cost to patients, and the province paid all costs. With the approximate 50% split in population due to the age cut-off, the predicted budget impact above and below the age cut-off within each treatment was nearly identical. To achieve maximum cost savings possible of $56,789,673 over three years, the province would need to provide fiberglass total contact casting to all patients, both above and below the age cut-off (Table 4).

Table 38. Predicted budget impact for patients with age above and below 65 years, and all patients, by treatment. Assumes 100% coverage with each treatment.

Patients	Treatment	Year 1	Year 2	Year 3	Total
Age above 65 years (total n=6,188)	Traditional dressing treatment	$0	$0	$0	$0
	Removable cast walker	-$6,928,066	-$7,497,821	-$8,114,903	-$22,540,790
	Irremovable cast walker	-$8,233,942	-$8,911,090	-$9,644,486	-$26,789,519
	Fiberglass total contact cast	-$8,721,775	-$9,439,041	-$ 10,215,889	-$28,376,704
Age below 65 years (total n=6,195)	Traditional dressing treatment	$0	$0	$0	$0
	Removable cast walker	-$6,936,920	-$7,507,403	-$8,125,273	-$22,569,596
	Irremovable cast walker	-$8,244,465	-$8,922,478	-$9,656,811	-$26,823,754
	Fiberglass total contact cast	-$8,732,921	-$9,451,104	-$10,228,944	-$28,412,969
All patients (total n=12,383)	Traditional dressing treatment	$0	$0	$0	$0
	Removable cast walker	-$12,346,365	-$13,361,713	-$14,461,402	-$40,169,480
	Irremovable cast walker	-$16,478,407	-$17,833,568	-$19,301,298	-$53,613,273
	Fiberglass total contact cast	-$17,454,696	-$18,890,145	-$20,444,833	-$56,789,673

This scenario is supported by the meta-analysis of the RCT literature, which found that TCCs, ICWs, and RCWs are similar with respect to time to healing; TCCs versus ICWs and TCCs versus RCWs are similar with respect to number of ulcers healed; and ICWs are superior

to RCW with respect to number of ulcers healed. This scenario also aligns with clinical guidelines recommending TCCs or ICWs as the standard of care for non-ischemic and non-infected wounds.

This scenario aligns with perspectives of BC health care providers who advocate for funding of offloading devices and perspectives of BC patients who have experienced healing as a result of using an offloading device. Many of the interviewed BC patients reported that they were unable to work as a result of their DFU; having access to timely, effective offloading treatment may help patients return back to work. The out-of-pocket cost of offloading devices (e.g., TCCs) was reported to be prohibitive for some patients, particularly low SES and other vulnerable populations. As a result, age-based funding would allow some of these marginalized populations to access offloading treatment, but it may restrict access to patients outside of the funded age group. Lastly, although in this scenario patients would have increased access to offloading treatment, availability of offloading devices may still vary across BC clinics, as accessibility appears to be tied to clinic funding in general.

The age-based funding scenario is characterized by several implementation considerations. Interviewed patients reported having little awareness of offloading treatment options available in BC (particularly TCCs) and wanting more information about all options available to them to avoid having to go through months of ineffective care; as a result, increased efforts to advertise these treatment options may be warranted. Interviewed BC patients and health care providers also reported a lack of funding for many foot care specialists in BC (e.g., podiatrists); as such, increased funding for foot care specialists in BC may need to be considered. Some patients reported having very little social support which presents as a barrier to them accessing offloading treatment (e.g., needing someone to drive them to appointments); establishing transportation options for these patients or offsetting the cost of travel by public transit or taxi may facilitate improved access. Lastly, both the interviewed BC patients and health care providers expressed concerns about the medical advice regarding offloading treatments provided in the province; additional education around offloading treatments and devices available may be warranted for BC health care providers.

This scenario aligns with the cost-utility analysis, which suggests that ICWs and TCCs offer increased benefit at a reduced cost for the treatment of uninfected DFUs. Resources allocated to ICWs and TCCs are predicted to have a greater health benefit than other treatments and offer a cost-savings. It also aligns with access to offloading devices in Ontario, Quebec, and Alberta, which offer various funding for different devices.

13.5 Conclusions

The results of budget impact analysis are summarized in Table 34. All scenarios considered suggest that the more patients with neuropathic DFU receive offloading devices, the greater the cost savings. Under the status quo, or provision of traditional dressing treatments only, high costs are driven by reduced device efficacy and increased treatment costs initially. Other devices with reduced treatment costs over months one to three, result in fewer unhealed patients and reduced treatment costs over the remainder of the year. This analysis makes the conservative assumption that costs for any patient with an unhealed ulcer over months 4 to 12 are identical, regardless of the treatment received, although the user may adjust this assumption in the accompanying spreadsheet.

In the second scenario considered, in which offloading treatments for neuropathic DFU are funded based on income, like PharmaCare, costs are shifted to patients. Although this scenario results in the lowest cost to the province with the most attractive total budget impact, this scenario assumes 100% adherence with offloading treatment, which is unlikely to be observed. For patients that are unable to pay their expected proportion of device costs, these patients may not receive optimal offloading treatment, resulted in poorer healing and increased costs to the province. This is likely to reduce the magnitude of cost savings predicted in this scenario.

In the third scenario considered, in which funding for offloading treatments is provided based on age, an age cut-off of 65 years was assumed. In BC, approximately 50% of neuropathic DFU occur in patients with age below 65 years. Findings in this scenario also suggest that cost savings are directly related to the number of patients treated. Perfect adherence is also assumed, which is more reasonable in this scenario, which includes no costs to patients. Cost savings predicted in

this scenario are slightly lower than scenario two, due to the lack of patient deductible and co-insurance.

One additional benefit of RCW and ICW treatments not explored in this analysis is the ability to reuse devices. Peters et al. describes a cohort of patients with DFU followed for 2.5 years, in which 60.5% of patients experienced development of an additional ulcer.[135] Use of either device is likely to increase healing compared to traditional wound management without offloading, therefore further reducing costs. This is one benefit not shared by the fiberglass TCC, which requires bi-weekly application.

13.5.1 *Limitations*

Guidelines may introduce bias due to funding from medical device companies for some organizations, however this review aimed to provide a comprehensive overview of the guidelines available; guidelines were not excluded based on potential conflict of interest or bias. Estimates of eligible population size are not exact. Although the best available evidence was used to define cases, these definitions are not validated. Because many offloading treatments are currently paid for out-of-pocket in BC, to private providers, the number of eligible patients may be underestimated, and costs of the status quo option are likely overestimated. Magnitude of estimation errors are unknown. Like the cost-effectiveness analysis (Section 13), this budget impact analysis also suffers from the data limitations informing clinical efficacy of treatments. Little is known about treatment efficacy after three months. Conservative assumptions were made which were identical across treatment, but validity of these assumptions is unknown. Similarly, perfect adherence with offloading treatments was assumed, which is unlikely to be realistic. In combination with overestimation of costs of the status quo, this results in overestimation of cost savings to the province with offloading treatments. Although these limitations reduce precision of predicted budget impacts, findings are clear. Increased use of offloading treatments for patients with neuropathic DFU in BC is likely to result in cost savings for the province.

14 Report Conclusions

This report presents the findings and conclusions of a provincial HTA on the use of offloading devices, specifically TCC, RCW and ICW, for diabetic neuropathic foot ulcers. Considered within the present HTA is evidence from patients, and clinicians, a survey of offloading practices across Canada, a systematic review of clinical effectiveness, a review of previous HTAs and clinical practice guidelines, an economic model and an implementation and budget impact analysis.

The review of guidelines identified fourteen documents of relevance. All recommended using an offloading device to minimize trauma to the active ulcer site. A non-removable knee high offloading device was most frequently recommended (TCC, or ICW) with many noting that due to forced adherence , non-removable devices may lead to better wound closure. The exception to this is for those with ischemic or infected wounds, for which an irremovable offloading device is contraindicated, RCW is recommended. Many guidelines describe the need for offloading decisions to consider factors such as the impact on patient lifestyle and occupation, affordability and accessibility, and patient support system.

One other HTA and one evidence review on this topic were identified; the HTA was conducted by HQO and the evidence review was conducted by CADTH. Both found TCC and ICW to be the most clinically effective and cost-effective options.

The survey of Canadian offloading device providers found little consistency in types of offloading devices offered to patients. Most respondents offer a variety of offloading devices to their patients, all but two providers among those who responded offer TCC. None of the respondents surveyed actively offer ICW. Based on the limited survey sample, it appears as though most offloading devices are not funded within Canada. TCC, although not covered, is reported by certain survey respondents as included in clinic hospital budgets for Alberta, Manitoba, and Quebec. TCC, RCW and a half shoe for forefoot ulcers are reported to be funded by Ontario's local health authority. Shoe and insoles are described by the provider as partially funded in Quebec, and are funded for prevention of recurrence after a healed ulcer or amputation in Alberta through AADL.

Using systematic review methodology, seventeen studies were identified that explored the clinical and safety effectiveness of offloading devices including TCC, ICW, and RCW. Of these, eight permitted inclusion in meta-analysis for two outcomes: ulcers healed and time to ulcer healing. The results from meta-analysis were mostly equivocal for both number of ulcers healed, and time to ulcer healing, with the exception of ICW and RCW for ulcers healed. Data suggests that ulcers are 1.4 times more likely to heal within 12 weeks when using ICW versus RCW (95% CI: 1.0 to 1.97).

Patient perspectives were captured using two methodologies: a rapid qualitative review of the literature and patient interviews. The rapid literature review was conducted by CADTH. Based on the 12 identified studies, patients and podiatrists identified the following barriers to adherence of offloading devices: mobility and autonomy, device mechanics, perceptions of the device's effectiveness, self-image and restoring social normalcy, device cost, and lack of information. These studies also identified that additional opportunities for a collaborative discussion between healthcare providers and their patient to allow for shared decision making in choice of offloading device may allow for better device adherence.

Interviews were conducted with eight patients living in BC; analysis of this data was largely consistent with what was found in the rapid review of literature. Broadly, patients reported following treatment recommendations for wearing their offloading device for the initial healing, although some struggled to wear their maintenance devices, which led to re-ulceration. Offloading devices were reported to impact patients' mobility, sleep, ability to shower, were associated with high cost and time-commitment for appointments, and resulted in stigma. Patients who received TCCs shared gratitude and appreciation for the effective treatment allowing the foot ulcer to heal very quickly. Patients reported wishing for more coverage of offloading devices in BC, as well as more accessibility to certain devices (primarily TCCs), and more education around the seriousness of the condition, options available, and what could happen if they do not wear the device.

Interviewed clinicians reported that based on their clinical experience, BC patients with diabetic foot ulcers DFUs are struggling to receive the right care, at the right time, and with the right

provider. Cost was reported to be a major barrier to accessing care, with diabetic offloading devices and certain specialists (e.g., podiatrists) not publicly funded in BC and indirect costs incurred from time off work. Diabetic foot ulcers were largely perceived to be a problem resulting from poverty, with social determinants of health contributing the certain groups of patients being more vulnerable than others. Care providers report frustration with this barrier and others, like the lack of access to a range of offloading devices, and lack of time to apply the devices and the lack of time to provide comprehensive care to their patients; these barriers result in high ulcer recurrence rates. Care providers differed in their opinions of where future funding for diabetic foot care in BC should be directed as there was considerable variability in the standard of care reported across the province, but all stressed the need for funding focused on preventative care.

A cost-utility analysis was conducted to compare cost and quality adjusted life years (QALYs) between offloading options for the treatment of uninfected diabetic foot ulcers, from the perspective of the publicly funded healthcare system in British Columbia, using a three-month time horizon. This cost-utility analysis suggests that ICWs and TCCs offer increased benefit and decreased costs for the treatment of uninfected DFUs. Resources allocated to ICWs and TCCs are predicted to have a greater health benefit than other treatments and offer a cost-savings.

Based on the evidence herein, three implementation scenarios were explored: 1) maintain status quo, 2) income-based funding for offloading treatments, and 3) age-based funding for offloading treatments. Treatments considered for funding are traditional dressings or no offloading (represents the status quo), RCW, ICW, and fiberglass TCC. Each has unique advantages and disadvantages including impact on health and non-health benefits, provincial expenditure, and access equity. A budget impact analysis conducted over a 3-year time horizon predicted that all offloading treatments will result in cost savings relative to the status quo, with the magnitude of cost savings being directly proportional to the number of patients for whom treatment is funded and likelihood of ulcer healing at 3 months.

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17 Appendix A – Jurisdictional Scan Survey Questions

Survey of Canadian Offloading Device Providers

Setting Provision

1. Within your province, what is the treatment pathway for people with type 1 or 2 diabetes with neuropathic foot ulcers?
2. Within your province, what which clinical practice guidelines or best practice recommendations are typically used?

Service Provision and Costs

3. Within your practice, which offloading device do you offer? (e.g.TCC, RCW, ICW, therapeutic shoes? etc.)
4. What are the perceived benefits and drawbacks for these offloading devices?
5. If any, which offloading devices are funded (in full or in part) and by whom?

18 Appendix B – Search Strategy

Medline

1 Diabetic Foot/

2 Foot Ulcer/

3 Diabetic Neuropathies/

4 ((diabet* adj4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* adj2 (foot or feet)) or (plantar adj2 (ulcer* or neuropath*))).tw,kf.

5 1 or 2 or 3 or 4

6 exp Diabetes Mellitus/

7 (diabet* or MODY or IDDM or NIDDM).tw,kf.

8 6 or 7

9 exp Foot Diseases/

10 exp Foot Dermatoses/

11 exp Foot Injuries/ or Wound Healing/

12 (skin ulcer* or ((foot or feet or toe or toes) adj2 (dermatos* or disease* or injur* or wound*)) or (wound* adj2 heal*)).tw,kf.

13 9 or 10 or 11 or 12

14 8 and 13

15 5 or 14

16 exp Casts, Surgical/

17 Walkers/

18 (cast or casts or casting* or total contact or TCC).tw,kf.

19 (air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthop?edic adj1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*).tw,kf.

20 (walker or walkers).tw,kf.

21 (offload* or off load*).tw,kf.

22 16 or 17 or 18 or 19 or 20 or 21

23 15 and 22

24 limit 23 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")

25 exp Technology Assessment, Biomedical/

26 (comparative study or meta analy* or metaanaly* or health technolog* assess*).tw,kf.

27 ((systematic* or critical or methodologic*) adj3 (review* or overview*)).tw,kf.

28 (groups or placebo* or random* or trial*).tw,kf.

29 25 or 26 or 27 or 28

30 23 and 29

31 24 or 30

32 animals/ not humans/

33 31 not 32

34 limit 33 to (english or french)

Embase

1 exp diabetic foot/

2 foot ulcer/

3 diabetic neuropathy/

4 ((diabet* adj4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* adj2 (foot or feet)) or (plantar adj2 (ulcer* or neuropath*))).tw,kw.

5 1 or 2 or 3 or 4

6 exp diabetes mellitus/

7 (diabet* or MODY or IDDM or NIDDM).tw,kw.

8 6 or 7

9 exp foot disease/

10 exp wound healing/

11 (skin ulcer* or ((foot or feet or toe or toes) adj2 (dermatos* or disease* or injur* or wound*)) or (wound* adj2 heal*)).tw,kw.

12 9 or 10 or 11

13 8 and 12

14 5 or 13

15 exp orthopedic cast/

16 walker/

17 (cast or casts or casting* or total contact or TCC).tw,kw.

18 (air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthop?edic adj1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*).tw,kw.

19 (walker or walkers).tw,kw.

20 (offload* or off load*).tw,kw.

21 15 or 16 or 17 or 18 or 19 or 20

22 14 and 21

23 limit 22 to (randomized controlled trial or controlled clinical trial)

24 limit 22 to (meta analysis or "systematic review")

25 exp randomized controlled trial/

26 exp controlled clinical trial/

27 exp randomization/

28 placebo.ti,ab.

29 (compare or compared or comparison or comparative).ti.

30 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.

31 exp controlled study/ or exp double blind procedure/

32 (crossover or cross over).ti,ab.

33 parallel group$1.ti,ab.

34 ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab.

35 (assigned or allocated).ti,ab.

36 (controlled adj7 (study or design or trial)).ti,ab.

37 (random* or trial*).ti.

38 exp biomedical technology assessment/

39 (comparative study or meta analy* or metaanaly* or health technolog* assess*).tw,kw.

40 ((systematic* or critical or methodologic*) adj3 (review* or overview*)).tw,kw.

41 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40

42 22 and 41

43 23 or 24 or 42

44 animal studies/ not human/

45 43 not 44

46 limit 45 to (english or french)

Cochrane Central Register of Controlled Trials

1 Diabetic Foot/

2 Foot Ulcer/

3 Diabetic Neuropathies/

4 ((diabet* adj4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* adj2 (foot or feet)) or (plantar adj2 (ulcer* or neuropath*))).tw.

5 1 or 2 or 3 or 4

6 exp Diabetes Mellitus/

7 (diabet* or MODY or IDDM or NIDDM).tw.

8 6 or 7

9 exp Foot Diseases/

10 exp Foot Dermatoses/

11 exp Foot Injuries/ or Wound Healing/

12 (skin ulcer* or ((foot or feet or toe or toes) adj2 (dermatos* or disease* or injur* or wound*)) or (wound* adj2 heal*)).tw.

13 9 or 10 or 11 or 12

14 8 and 13

15 5 or 14

16 exp Casts, Surgical/

17 Walkers/

18 (cast or casts or casting* or total contact or TCC).tw.

19 (air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthop?edic adj1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*).tw.

20 (walker or walkers).tw.

21 (offload* or off load*).tw.

22 16 or 17 or 18 or 19 or 20 or 21

23 15 and 22

Cochrane Database of Systematic Reviews

1 ((diabet* adj4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* adj2 (foot or feet)) or (plantar adj2 (ulcer* or neuropath*))).tw.

2 (diabet* or MODY or IDDM or NIDDM).tw.

3 (skin ulcer* or ((foot or feet or toe or toes) adj2 (dermatos* or disease* or injur* or wound*)) or (wound* adj2 heal*)).tw.

4 2 and 3

5 1 or 4

6 (cast or casts or casting* or total contact or TCC).tw.

7 (air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthop?edic adj1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*).tw.

8 (walker or walkers).tw.

9 (offload* or off load*).tw.

10 6 or 7 or 8 or 9

11 5 and 10

CINAHL

1. (MH "Diabetic Foot") OR (MH "Foot Ulcer") OR (MH "Diabetic Neuropathies")) OR TI (((diabet* N4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* N2 (foot or feet)) or (plantar N2 (ulcer* or neuropath*)))) OR AB (((diabet* N4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* N2 (foot or feet)) or (plantar N2 (ulcer* or neuropath*))))
2. (MH "Diabetes Mellitus+") OR TI ((diabet* or MODY or IDDM or NIDDM)) OR AB ((diabet* or MODY or IDDM or NIDDM))
3. ((MH "Foot Diseases+") OR (MH "Foot Injuries") OR (MH "Wound Healing")) OR TI ((skin ulcer* or ((foot or feet or toe or toes) N2 (dermatos* or disease* or injur* or

wound*)) or (wound* N2 heal*))) OR AB ((skin ulcer* or ((foot or feet or toe or toes) N2 (dermatos* or disease* or injur* or wound*)) or (wound* N2 heal*)))

4. 2 and 3
5. 1 or 4
6. ((MH "Casts") OR (MH "Walkers")) OR TI ((cast or casts or casting* or total contact or TCC)) OR AB ((cast or casts or casting* or total contact or TCC)) OR TI ((walker or walkers)) OR AB ((walker or walkers)) OR TI ((offload* or off load*)) OR AB ((offload* or off load*))
7. AB ((air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthopedic N1 boot*) or (orthopaedic N1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*)) OR TI ((air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthopedic N1 boot*) or (orthopaedic N1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*))
8. 6 or 7
9. 5 and 8

   (MH "Randomized Controlled Trials") OR (MH "Double-Blind Studies") OR (MH "Triple-Blind Studies") OR (MH "Single-Blind Studies") OR (MH "Comparative Studies") OR (MH "Random Assignment") OR (MH "Crossover Design") OR (MH "Pretest-Posttest Design") OR (MH "Pretest-Posttest Control Group Design") OR (MH "Cluster Sample") OR (MH "Placebos")
10. TI (assigned OR allocated OR control OR random* OR RCT OR placebo*) OR AB (assigned OR allocated OR control OR random* OR RCT OR placebo*)
11. TI comparative
12. 10 or 11 or 12
13. 9 and 13
14. Limit to English Language

Web of Science

1. TOPIC: ((((diabet* N4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* N2 (foot or feet)) or (plantar N2 (ulcer* or

neuropath*))))) OR TITLE: ((((diabet* N4 (foot or feet or ulcer* or toe or toes or plantar* or neuropath* or neural* or wound*)) or DFU* or (ulcer* N2 (foot or feet)) or (plantar N2 (ulcer* or neuropath*)))))

2. TOPIC: ((diabet* or MODY or IDDM or NIDDM)) OR TITLE: ((diabet* or MODY or IDDM or NIDDM))
3. TOPIC: (((skin ulcer* or ((foot or feet or toe or toes) N2 (dermatos* or disease* or injur* or wound*)) or (wound* N2 heal*)))) OR TITLE: (((skin ulcer* or ((foot or feet or toe or toes) N2 (dermatos* or disease* or injur* or wound*)) or (wound* N2 heal*))))
4. 2 and 3
5. 1 or 4
6. TOPIC: ((walker or walkers or offload* or off load*)) OR TITLE: ((walker or walkers or offload* or off load*))
7. TOPIC: (((air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthopedic N1 boot*) or (orthopaedic N1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*))) OR TITLE: (((air boot* or air cast* or aircast* or brace or bracing or cam boot* or cam walker* or ITCC or optima diab or (orthopedic N1 boot*) or (orthopaedic N1 boot*) or prefab or removable boot* or rom boot* or stabil d or stabild or walking boot*)))
8. 6 or 7
9. 5 and 8
10. Title:(comparative study or meta analysis or metanalysis or randomized controlled trial OR controlled clinical trial OR systematic review)
11. Topic:(comparative study or meta analysis or metanalysis or randomized controlled trial OR controlled clinical trial OR systematic review)
12. 10 or 11
13. 9 and 12

19 Appendix C – Systematic Review of Clinical Effectiveness Tables and Meta-Analysis

19.1 Table of Excluded Studies

Table 39. Studies Excluded during Full-text Review

Author	Reason for Exclusion
Agas et al. (2006)[136]	Full-text not available
Alvarez et al. (2017)[137]	Comparator not of interest
Amendola et al. (2002)[138]	Population not of interest
Armstrong et al. (2001)[82]	Study design not of interest
Boulton et al. (2003)[139]	Study design not of interest
Bus et al. (2009)[140]	Study design not of interest
Caravaggi et al. (2007)[89]	Full-text not available
Chakraborty et al. (2015)[141]	Intervention not of interest
Ersen et al. (2020)[97]	Population not of interest
Ganguly et al. (2008)[142]	Full-text not available
Gotz et al. (2017)[143]	Outcomes not of interest
Isrctn et al. (2014)[144]	Full-text not available
Isrctn et al. (2016)[145]	Full-text not available
Jain et al. (2020)[146]	Intervention not of interest
Jeffcoate et al. (2017)[147]	Comparator not of interest
Jeffcoate et al. (2004)[148]	Full-text not available
Kaplan et al. (1988)[149]	Study design not of interest
Katz et al. (2004)[150]	Duplicate
Katz et al. (2005)[151]	Duplicate
Katz et al. (2004)[150]	Duplicate
Lewis et al. (2003)[152]	Full-text not available
Maluf et al. (2004)[153]	Duplicate
Martin et al. (1996)[154]	Population not of interest
Matricali et al. (2003)[155]	Study design not of interest
Miyan et al. (2014)[156]	Intervention not of interest
Mohammedi et al. (2016)[157]	Full-text not available
Nabuurs-Franssen et al. (2005)[158]	Study design not of interest

Najafi et al. (2014)[159]	Duplicate
Faglia et al. (2009)[90]	Full-text not available
Moody et al. (2009)[160]	Full-text not available
Piaggesi et al. (2016)[84]	Comparator not of interest
Piaggesi et al. (2014)[161]	Full-text not available
Sahu et al. (2018)[162]	Comparator not of interest
Salsich et al. (2005)[163]	Comparator not of interest
Thompson et al. (2019)[164]	Comparator not of interest
Vallini et al. (2012)[165]	Full-text not available
Van de Weg et al. (2008)[96]	Comparator not of interest
Van Netten et al. (2014)[166]	Full-text not available
Van Netten et al. (2015)[167]	Full-text not available
Wang et al. (2015)[168]	Comparator not of interest
Watkinson et al. (2002)[169]	Study design not of interest
Yadav et al. (2015)[170]	Duplicate

19.2 Characteristics of Included Randomized Controlled Trial Studies

Table 40. Characteristics of Included Randomized Studies

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
Armstrong et al.[82] Italy (2001) Trial #: NR Funding: NR	**Inclusion:** clinically significant loss of protective sensation (.25 V) as measured with a biothesiometer (Biomedical Instrument, Newbury, OH) (18,19), at least one palpable foot pulse or a transcutaneous oximetry (TcPO2) measurement higher than 40 mmHg at the level of the dorsum of the forefoot, and a neuropathic plantar diabetic foot ulcer corresponding to grade 1A **Exclusion:** active infection, were unable to walk without wheelchair assistance, had wounds in locations on the heel, rear foot, or area other than the plantar aspect of the foot,or had severe peripheral vascular disease	**Total Sample Size (% Female):** n=63 (17.5%) **Mean Age:** NR **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** Stage 1A **Location of ulcer:** NR	**Intervention #1:** TCC (n=19) Description: NR **Intervention #2:** RCW (n=20) Description: aircast diabetic walker **Intervention #3:** Half-shoe (n=24) Description: NR	**Analysis Type:** NR **Follow-up (months):** 12 weeks **Outcomes:** - activity (steps per day) - change in wound size - proportion of completed wound healing at 12 weeks
Armstrong et al.[81] USA (2005) Trial #: NR Funding: NR	**Inclusion:** loss of protective sensation (>25 V) as measured with a vibration perception threshold meter, at least one palpable foot pulse, and a neuropathic plantar diabetic fool ulcer corresponding to grade lA (superficial, not extending to tendon, capsule, or bone, according to the University of Texas Diabetic Foot Wound Classification System	**Total Sample Size (% Female):** n=50 (12%) **Mean Age:** 65.6 **Type of Diabetes:** Unspecified	**Intervention #1:** ICW (n=23) Description: RCW rendered irremoveable by wrapping it entirely in cohesive bandage (described as iTCC)	**Analysis Type:** ITT **Follow-up (months):** 12 weeks **Outcomes:** - % healed in 12 weeks

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
	Exclusion: active infection; unable to walk without a wheelchair; with wounds in locations on the heel, rearfoot, or a location other than the plantar aspect of the foot; or with severe peripheral vascular disease	**Initial ulcer stage/classification:** Stage 1A **Location of ulcer:** Plantar (not heel or rearfoot)	**Intervention #2:** RCW (n=27) Description: same RCW brand as ICW	- Kaplan-Meier wound survival - mean time to closure
Armstrong et al.[80] USA (2008) Trial #: NR Funding: NR	**Inclusion:** Diagnosis of diabetes mellitus prior to enrollment; clinically significant loss of protective sensation (.25 V) as measured with a biothesiometer (Biomedical Instrument, Newbury, OH) (18,19), at least one palpable foot pulse or a transcutaneous oximetry (TcPO2) measurement higher than 40 mmHg at the level of the dorsum of the forefoot, and a neuropathic plantar diabetic foot ulcer corresponding to grade 1A **Exclusion:** active infection, were unable to walk without wheelchair assistance, had wounds in locations on the heel, rear foot, or area other than the plantar aspect of the foot,or had notable peripheral vascular disease	**Total Sample Size (% Female):** n=63 (17.5%) **Mean Age:** NR **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** Stage 1A **Location of ulcer:** NR	**Intervention #1:** TCC (n=19) Description: NR **Intervention #2:** RCW (n=20) Description: aircast diabetic walker **Intervention #3:** Half-shoe (n=24) Description: NR	**Analysis Type:** NR **Follow-up (months):** 12 weeks **Outcomes:** - HRQOL
Bus et al.[87] Netherlands/Germany (2018) Trial #: ISRCTN89989776	**Inclusion:** age above 18 and below 85years; confirmed type 1 or type 2 diabetes mellitus with glyco- sylated haemoglobin <12% (<108 mmol/mol); absence of protective sensation on the plantar foot based on abnormal	**Total Sample Size (% Female):** n=60 (20%) **Mean Age:** 62.6	**Intervention #1:** BTCC (n=20) Description: TCC, knee high cast boot	**Analysis Type:** ITT **Follow-up (months):** 20 weeks **Outcomes:**

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
Funding: NR	Semmes-Weinstein monofilament or abnormal 128 Hz tun- ing fork measurements (27); and a full-thickness ulcer (i.e., extending through the dermis) on the plantar forefoot that had been present for at least 2 weeks (27), with a surface area between 0·25 and 25 cm2 post-debridement and classified as a University of Texas grade 1A or 2A ulcer (28). **Exclusion:** immune system, systemic or connec- tive tissue disease; current malignancy; recent (<6 weeks) treatment with immunosuppressive or chemotherapeutic agents; progressive renal dysfunction (estimated glomerular filtration rate < 30 ml/min or creatinine level > 300 μmol/l) or worsening in the previous 6 months (>20% per month) or severe nephrotic syndrome (>3g protein loss per day); additional ipsilateral plantar midfoot or heel ulcer; necrosis, purulence or sinus tracts in the ulcer that cannot be removed by debridement; inadequate peripheral vascular circulation, that is, ankle-brachial pressure index <0·8 or toe systolic blood pressure <40 mmHg; clinical signs of infection, grade 2 or higher (29); use of antibiotics; severe foot deformity, that is, any amputation other than the lesser toes, Charcot midfoot deformity or ankle equines; inability to walk unaided; or inability to follow study instructions.	**Type of Diabetes:** Type 1 and 2 **Initial ulcer stage/classification:** Stage 1A or 2A **Location of ulcer:** Forefoot	**Intervention #2:** Cast shoe (n=20) Description: ankle high cast shoe **Intervention #3:** FOS (n=20) Description: forefoot offloading device	- % of ulcers healed at 12 weeks - % of ulcers healed at 20 weeks - # complications - daily stride count - non-adherence - peak pressure - time to healing - ulcer surface area reduction in four weeks

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
Caravaggi et al.[88] Italy (2000) Trial #: NR Funding: NR	**Inclusion:** insensitive to Semmes-Weintsein 5.07 monofilament and had a vibration perception threshold of 25 V measured on the malleolous with a biothesiometer **Exclusion:** clinical presence of deep or superficial tissue infection or underlying osteomyelitis, transcutaneous PO2, severe problem in maintaining equilibrium, severe visual deficit, skin lesions of foot other than ulcer understudy, or leg amputation	**Total Sample Size (% Female):** n= 50 (32%) **Mean Age:** 59.9 **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** NR **Location of ulcer:** NR	**Intervention #1:** TCC (n=26) Description: fiberglass; offloading platform attached to cast - either stirrups for midfoot ulcer, or rubber heel for forefoot ulcer **Intervention #2:** Therapeutic shoe (n=24) Description: cloth therapeutic shoe with rocker bottom sole and rolling point situated beside metatarsal arch during walking	**Analysis Type:** NR **Follow-up (months):** 30 weeks **Outcomes:** - % of ulcers healed - acceptance of treatment - reduction in ulcer size - side effects
Caravaggi et al.[89] Italy (2007) Trial #: NR Funding: NR	**Inclusion:** insensitivity to 10 g monofilament and vibration perception threshold measured by biothesiometer at 1nalleolus or at least 25 volts, and presented with a neuropathic ulcer on the whole part of the plantar surface of the foot, includi ng ulcers correlated ,with Charcot neuroarthropathy deformities. **Exclusion:** superficial tissue infection, osteomyelitis, Tc PO 2 , ankle brachial index >0.6, severe visual deficit, severe problems of equilibrium, amputation of the controlateral limb, and bilateral plantar ulcers	**Total Sample Size (% Female):** n=58 (NR) **Mean Age:** NR **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** NR **Location of ulcer:** NR	**Intervention #1:** ICW (n=29) Description: fiberglass; offloading platform attached to cast - either stirrups for midfoot ulcer, or rubber heel for forefoot ulcer **Intervention #2:** Aircast pneumatic walker (n=29)	**Analysis Type:** NR **Follow-up (months):** 90 weeks **Outcomes:** - % of ulcers healed - complications - mean healing time (days)

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
			Description: a semi-rigid plastic shell surrounding the limb, a ren1ovable front panel allowing easy access to the injured site	
Faglia et al.[90] Italy (2010) Trial #: NCT01005264 Funding: NR	**Inclusion:** presence of a neuropathic plantar forefoot ulcer with an area graded IA according to the University of Texas Classification of Diabetic Wounds. Peripheral neuropathy was diagnosed based on insensitivity to a 10-g Semmes-Weinstein monofilament in more than six of nine areas of the foot and by a vibration perception threshold measured by biothesiometer at the malleolus of> 25 V. **Exclusion:** presence of an ankle-brachial pressure index <0.9 and/or transcutaneous oxygen tension <50 mmHg tested on the dorsum of the foot and clinical signs of infection. Both the probe-to-bone maneuver and standard X-ray examination of the foot were required to be negative for osteomyelitis; use of steroids or antimitotic drugs, the presence of visual problems that could impair balance, an active ulcer on the contralateral foot, previous major amputation of Lhe contralateral limb, previous or current deep venous thrombosis of the leg, or mental disorder interfering with patient compliance.	**Total Sample Size (% Female):** n=45 (33%) **Mean Age:** 60.4 **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** Stage 1A **Location of ulcer:** Plantar, forefoot	**Intervention #1:** TCC (n=23) Description: fiberglass; offloading platform attached to cast - either stirrups for midfoot ulcer, or rubber heel for forefoot ulcer **Intervention #2:** Stabil-D walker cast (removable) (n=22) Description: rigid , boat-shaped, and fully rocker bouom sole: its rounded extremities (at the heel and tiptoe) facilitate gait, and its middle section improves the 1n id-stance phase.	**Analysis Type:** NR **Follow-up (months):** 90 weeks **Outcomes:** - days to healing - decrease in ulcer size - rate of complete healing

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
Gutekunst et al.[91] USA (2011) Trial #: NR Funding: National Institutes of Health	**Inclusion:** DM, PN, and plantar ulceration **Exclusion:** infection, lower-extremity ischemia, or cellulitis	**Total Sample Size (% Female):** n=23 (17.4%) **Mean Age:** 54 **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** Stage 1A - 3A **Location of ulcer:** Forefoot or midfoot	**Intervention #1:** TCC (n=11) Description: TCC was completed using plaster and fiberglass wrapping; pressure insole fitted within TCC **Intervention #2:** RCW (n=12) Description: pressure insole fitted within RCW boot	**Analysis Type:** NR **Follow-up (months):** NR **Outcomes:** - % of ulcers healed - contact area - contact pressure - contact time - time to healing whole-foot and regional loads
Katz et al.[86] USA (2005) Trial #: NR Funding: NR	**Inclusion:** chronic, nonischemic, non infected University of Texas stage LA or I IA ulcers. All patients had n1oderate Losevere neuropathy, with a loss of protective sensation, defined as a neuropathy disability score >=6 and a biothesiometer vibration perception threshold score >=25 volts at the apex of the hallux on the affected side. **Exclusion:** clinical evidence of active infection at the ulcer site: active Charcot neuroanhropathy; significant peripheral arterial disease, denned as an absent dorsalis pedis or posterior tibial pulse: an inability to \valk: or if they did not n1eet the entry criteria. lf the patient had n1ore than one ulcer. the largest	**Total Sample Size (% Female):** n=41 (32%) **Median Age:** 50.9 **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** Stage 1A or 2A (University of Texas Diabetic Wound Classification) **Location of ulcer:** Forefoot, midfoot, or heel	**Intervention #1:** TCC (n=20) Description: fiberglass **Intervention #2:** ICW (n=21) Description: RCW rendered irremoveable by wrapping it around the lower leg	**Analysis Type:** NR **Follow-up (months):** 12 weeks (or until complete healing of ulcer) **Outcomes:** - cost - complication rates - median heal time - prevalence of complete wound healing - time to place and remove devices

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
	ulcer \vas considered the index ulcer for study purposes.			
Lavery et al.[83] USA (2015) Trial #: NR Funding: National Institute of Health and National Institute of Diabetes and Digestive and Kidney Diseases	**Inclusion:** Diabetic patients with grade UT1A or UT2A forefoot ulcers on the sole of the foot were enrolled. **Exclusion:** inability to care for their ulcer during the study period (e.g. because of vacation, hospitalisation and disability), widespread malignancy, systematically immunecompromising disease, severe peripheral vascular disease (ABI<0·60 or transcutaneous oxygen<25 mm/Hg), alcohol or substance abuse within 6 months, untreated osteomyelitis or Charcot arthropathy with residual deformity that was too severe to allow proper fit of the removable walking boot, and patients with postural stability that was not adequate to safely ambulate in a TCC or walking boot	**Total Sample Size (% Female):** n=73 (43.8%) **Mean Age:** NR **Type of Diabetes:** Type 1 and 2 **Initial ulcer stage/classification:** Stage 1A or 2A **Location of ulcer:** NR	**Intervention #1:** TCC (n=23) Description: NR **Intervention #2:** Healing sandals (n=23) Description: NR **Intervention #3:** Shear walker (n=27) Description: RCW designed to reduce pressure and shear forces on plantar surface	**Analysis Type:** ITT and PP **Follow-up (months):** 12 weeks **Outcomes:** - activity - adverse events - subject satisfaction - time to heal - wound healing - wound size
Mueller et al.[92] USA (1989) Trial #: NR Funding: Foundation for Physical Therapy	**Inclusion:** Diagnosed with diabetes mellitus and currently had a plantar ulcer but no evidence of gross infection (no significant edema or drainage), osteomyelitis (determined by radiograph or radionuclide scans), or gangrene (visibly discolored or necrotic tissue).	**Total Sample Size (% Female):** n=40 (32.5%) **Mean Age:** 54.5 **Type of Diabetes:** Type 1 and 2	**Intervention #1:** TCC (n=21) Description: A total contact plaster shell was then molded around the lower leg. The shell was reinforced with plaster	**Analysis Type:** NR **Follow-up (months):** NR **Outcomes:** - % of ulcers healed

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
	Exclusion: NR	**Initial ulcer stage/classification:** Grade 1 or 2 (Wagner Grading System) **Location of ulcer:** Toes, forefoot, midfoot, heel	splints, and a walking heel was attached to the plantar surface. A fiberglass roll was applied around the plaster for extra durability and to allow bearing weight sooner than would be allowed with plaster alone. **Intervention #2:** Traditional dressing treatment (n=19) Description: NR	- complications - time to healing
Mueller et al.[94] USA (2003) Trial #: NR Funding: National Center for Medica Rehabilitation Research and the National Institutes of Health	**Inclusion:** History of diabetes mellitus, loss of protective sensation (unable to sense the 5.07 Semmes-Weinstien monofilament on at least one location on the plantar aspect of the foot), limitation of ankle dorsiflexion to <= 5 degrees, a lpalpable ankle pulse, and a recurrent or nonhealing ulcer on the forefoot (Grade II on the Wagner scale). A recurrent or nonhealing ulcer was defined as two or more occurrences of a plantar ulcer or the failure of a plantar ulcer to heal with conservative treatment (ie: dressing changes and footwear modifications) **Exclusion:** Neurological problem complicating the rehabilitation, history of Charcot fractures of the hindfoot, were unable to tolerate the anesthesia required for	**Total Sample Size (% Female):** n=64 (23.4%) **Mean Age:** 56 **Type of Diabetes:** Type 1 and 2 **Initial ulcer stage/classification:** Grade 2 (Wagner Grading System) **Location of ulcer:** Plantar	**Intervention #1:** TCC (n=33) Description: NR **Intervention #2:** TCC with achilles tendon lengthening (n=31) Description: ATL surgery followed by TCC	**Analysis Type:** NR **Follow-up (months):** 5 years **Outcomes:** - death - falls - heel ulcer - infection - reoccurrences - stepdown to RCT - superficial abrasion - transmetatarsal amputation - time to ulcer healing - time to recurrence - toe amputation - ulcer healing - untolerated initial intervention

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
	Achilles tendon lengthening, or if it was thought that they would not benefit from an Achilleds denton lengthening (ie: they were not able to walk).			
Mueller et al.[93] USA (2004) Trial #: NR Funding: NR	**Inclusion:** History of diabetes mellitus, loss of protective sensation (unable to sense the 5.07 Semmes-Weinstien monofilament on at least one location on the plantar aspect of the foot), limitation of ankle dorsiflexion to <= 5 degrees, a lpalpable ankle pulse, and a recurrent or nonhealing ulcer on the forefoot (Grade II on the Wagner scale). A recurrent or nonhealing ulcer was defined as two or more occurrences of a plantar ulcer or the failure of a plantar ulcer to heal with conservative treatment (ie: dressing changes and footwear modifications) **Exclusion:** Neurological problem complicating the rehabilitation, history of Charcot fractures of the hindfoot, were unable to tolerate the anesthesia required for Achilles tendon lengthening, or if it was thought that they would not benefit from an Achilleds denton lengthening (ie: they were not able to walk).	**Total Sample Size (% Female):** n=28 (25%) **Mean Age:** 54.6 **Type of Diabetes:** Type 1 and 2 **Initial ulcer stage/classification:** Grade 2 (Wagner Grading System) **Location of ulcer:** Plantar	**Intervention #1:** TCC (n=14) Description: NR **Intervention #2:** TCC with achilles tendon lengthening (n=14) Description: ATL surgery followed by TCC	**Analysis Type:** NR **Follow-up (months):** 8 months **Outcomes:** - reoccurrence rate - SF-36
Najafi et al.[95] USA/QATAR (2017) Trial #: NR	**Inclusion:** Confirmed diabetes and peripheral neuropathy, age 18 or older with noninfected, non ischemic, plantar neuropathic foot ulcers	**Total Sample Size (% Female):** n=49 (8%) **Mean Age:** 53.7	**Intervention #1:** RCW (n=26) Description: NR	**Analysis Type:** NR **Follow-up (months):** 12 weeks

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
Funding: Qatar National Research Foundation	**Exclusion:** Major foot amputation, active Charcot arthropathy, ankle brachial index of 0.5 or less, history of alcohol or substance abuse within 6 months, or unable to keep research appointments. If subjects had noncompressible vessels (ABI>1.2), a toe brachial index >0.65 was required for enrollment. Those that could not be accomodated in a standard removable cast walker or were unable to walk a distance of minmum 20 minutes with or without an assistive device.	**Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** NR **Location of ulcer:** Plantar	**Intervention #2:** ICW (n=23) Description: RCW rendered irremoveable by wrapping it around the lower leg with fibergalss	**Outcomes:** - ulcer healing
Piagessi et al.[85] Italy (2007) Trial #: NR Funding: NR	**Inclusion:** Type 1 or type 2 diabetes for a period of at least 5 years, peripheral neuropathy as highlighted by insensitivity to a 10-g monofilament and by a vibration perception threshold measured at malleolus of at least 25 volts, and a forefoot plantar ulcer for a period of at least 3 weeks with an area of wider than 1cm^2 grade IA or IIA according to the Texas University classification **Exclusion:** Peripheral vascular disease with an ankle-brachial pressure index <0.9; presence of clinical signs of infection, including edema, erithema, increased local skin temperature, secretion, fever, and leukocytosis, confirmed by culture exams; previous ulcer in the same site in the last 6 months; probing to bone and/or radiographic signs of osteomyelitis; Charcot's neuroarthropathy of the foot; bilateral ulceration; serum creatinine >2mg/dL;	**Total Sample Size (% Female):** n=40 (NR) **Mean Age:** 60.5 **Type of Diabetes:** Type 1 and 2 **Initial ulcer stage/classification:** Grade 1A or 2A **Location of ulcer:** Plantar, forefoot	**Intervention #1:** TCC (n=20) Description: fiberglass boot **Intervention #2:** ICW (n=20) Description: Optima Diab device, secured to the patient's leg with a plastic nonremovable lace	**Analysis Type:** ITT **Follow-up (months):** 12 weeks **Outcomes:** - local infection - maceration - partial rupture of TCC - single episode of transient paresthesia - superficial emathoma of the calf due to accident - time to ulcer healing - ulcer healing

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
	any systemic pathology or therapy possible interfering with the healing process; severe visual or motor impairment that could expose the patient to risk of accidents while participating in the study; and/or a life expectancy shorter than 1 year			
Piaggesi et al.[84] Italy (2016) Trial #: NR Funding: NR	**Inclusion:** type 1 or type 2 diabetes lasting for at least 5 years; presence of a forefoot plantar ulcer wider than 1 cm2, staged IA or IIA according to the University of Texas Diabetic Wound Classification,1 lasting at least 6 weeks; ankle-brachial pressure index ≥0.9 with 2 palpable pulses in the affected foot **Exclusion:** presence of infection according to the criteria of the Infectious Disease Society of America guidelines20; surgical procedure in the previous year on the affected foot; inability to actively dorsiflex the affected foot; involvement of deeper foot structures, that is, probe-to-bone negative; presence of other lesions in the same or contralateral foot; diagnosis of acute or chronic Charcot foot, either in the affected or contralateral foot; lower limb edema; chronic renal insufficiency as demonstrated by creatinine >2 mg/dL; previous minor or major amputations in the affected or contralateral limb; nonambulatory; body mass index >35; visual impairment; metabolic decompensation with HbA1c >10%; cancer; HIV-positive; or any local or	**Total Sample Size (% Female):** n=60 (40%) **Mean Age:** 61.17 **Type of Diabetes:** Type 1 and 2 **Initial ulcer stage/classification:** Stage 1A or 2A (University of Texas Diabetic Wound Classification **Location of ulcer:** Forefoot	**Intervention #1:** TCC (n=20) Description: Fiberglass **Intervention #2:** ICW (n=20) Description: NR **Intervention #3:** RCW (n=20) Description: NR	**Analysis Type:** PP **Follow-up (months):** 90 days (or until complete healing of ulcer) **Outcomes:** - device satisfaction - number of adverse events - prevalence of complete healing - time to healing - ulcer survival - ulcer size reduction

Author	Inclusion/Exclusion	Demographic	Intervention	Analysis
	systemic conditions that may impair tissue repair.			
Van De Weg et al.[96] Netherlands (2008) Trial #: NR Funding: Convatec Netherlands and the OFOM (Ontwikkelingfonds Orthopedisch Maatscheoisel)	**Inclusion:** Confirmed diabetes, sensory neuropathy tested by a quantitative somatosensory threshold test using the Semmes-Weinstein 5.07 (10g) monofilament (on first and fifth metatarsal heads, medial and lateral midfoot and heel), and a plantar ulcer Grade I or II using the Wagner scale. **Exclusion:** Unable to walk indoors, with dementia or life-threatening co-morbidity, ankle/brachial index M0.4 and/or osteomyelitis (determined by plain radiograph)	**Total Sample Size (% Female):** n=43 (20.9%) **Mean Age:** 61.7 **Type of Diabetes:** Unspecified **Initial ulcer stage/classification:** Grade 1 or 2 (Wagner Grading System) **Location of ulcer:** Plantar	**Intervention #1:** TCC (n=23) Description: A well-molded and minimally padded non-removable below-knee cast that maintains contact with the entire plantar aspect of the foot and lower leg **Intervention #2:** Custom-made temporary footwear (n=20) Description: Removable; The CTF was custom-made of felt and supplied with a rigid leather socket stiffened with Rhenoflex, a composite of rubber and plastic with thermoplastic properties	**Analysis Type:** ITT **Follow-up (months):** 16 weeks **Outcomes:** - amputations - time to ulcer healing - ulcer healing

Abbreviations: ABI: ankle brachial index; ATL: achilles tendon lengthening; BTCC: bivalve total contact cast; DM: diabetic mellitus; FOS: forefoot offloading device; HRQoL: health-related quality of life; ICW: irremovable cast walker; iTCC: instant total contact cast; ITT: intention to treat; NR: not reported; OH:

Ohio; PN: peripheral neuropathy; PP: per protocol; RCT: randomized controlled trials; RCW: removable cast walker; SF-36: short form survey 36 item; TCC: total contact cast; USA: United States of America

19.3 **Meta-Analysis Forest Plots: Ulcers Healed at Three Month Follow-up**

Figure 31. Meta-Analysis TCC vs. ICW for Ulcers Healed at 12 Weeks

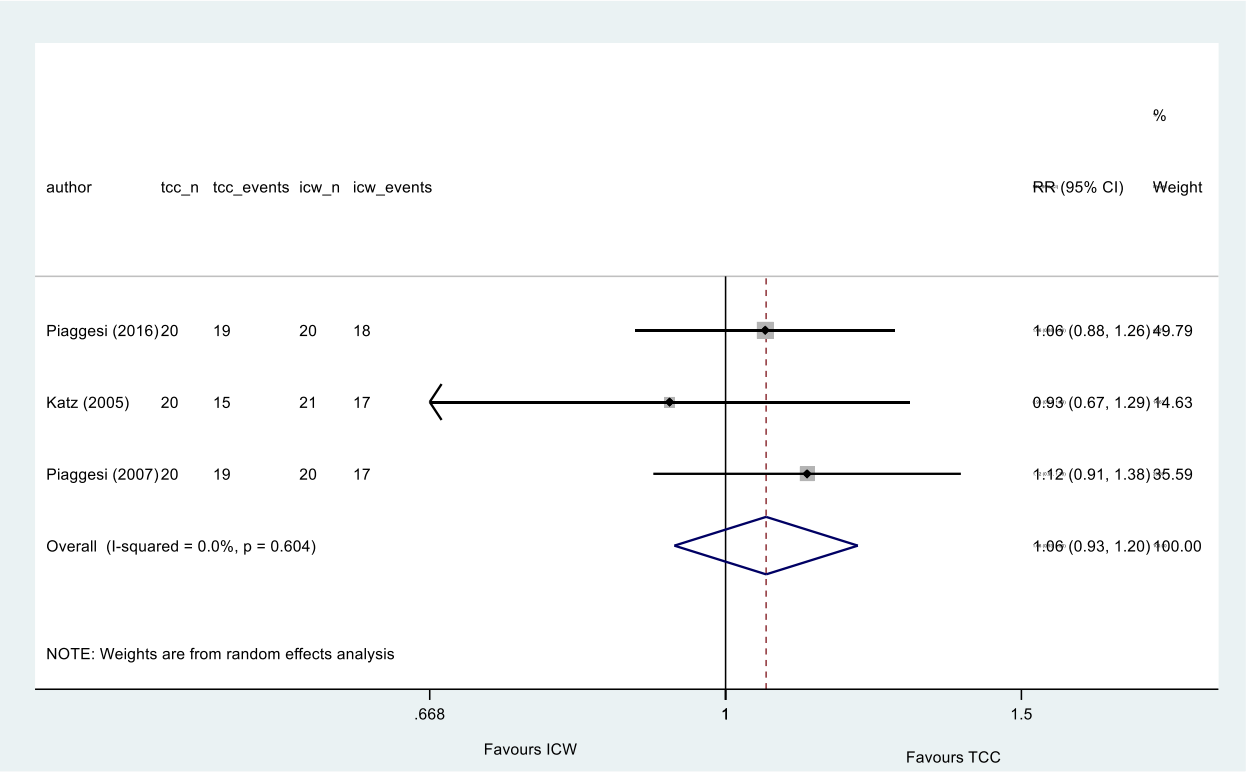


Figure 32. Meta-Analysis for Ulcers Healed TCC vs. RCW at 12 Weeks

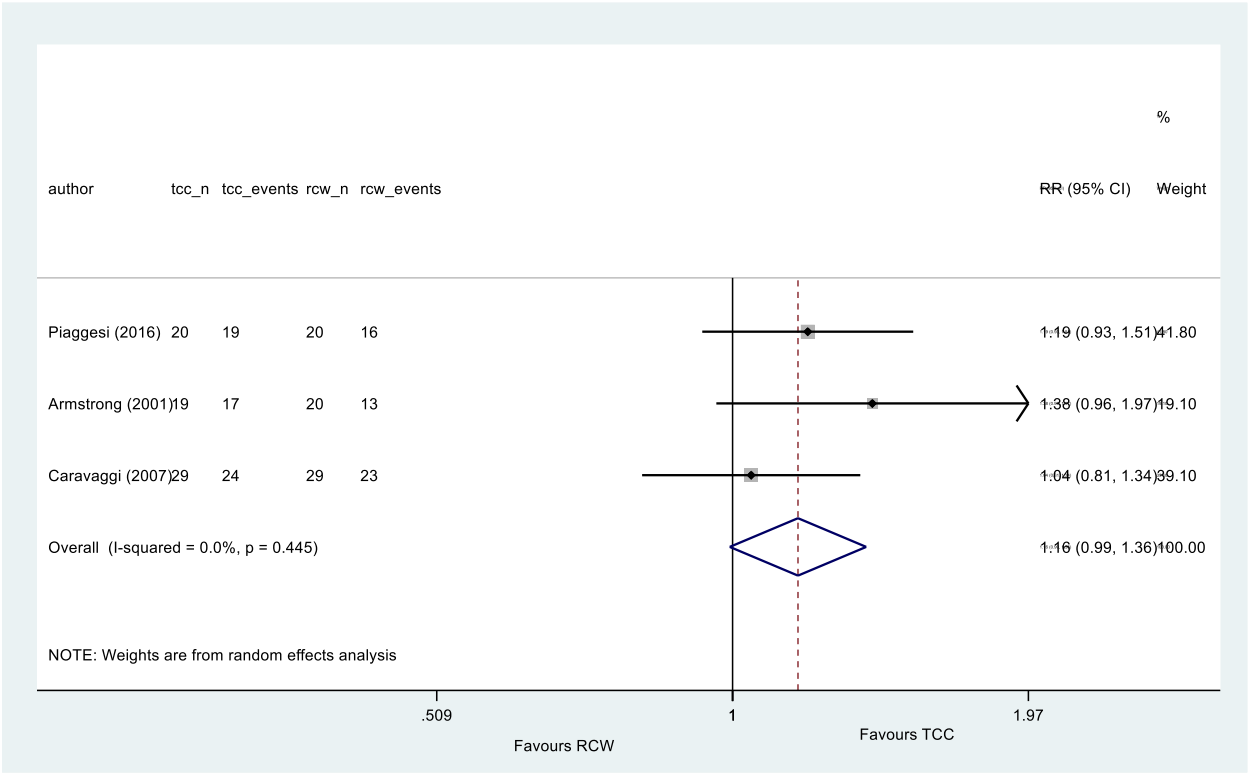
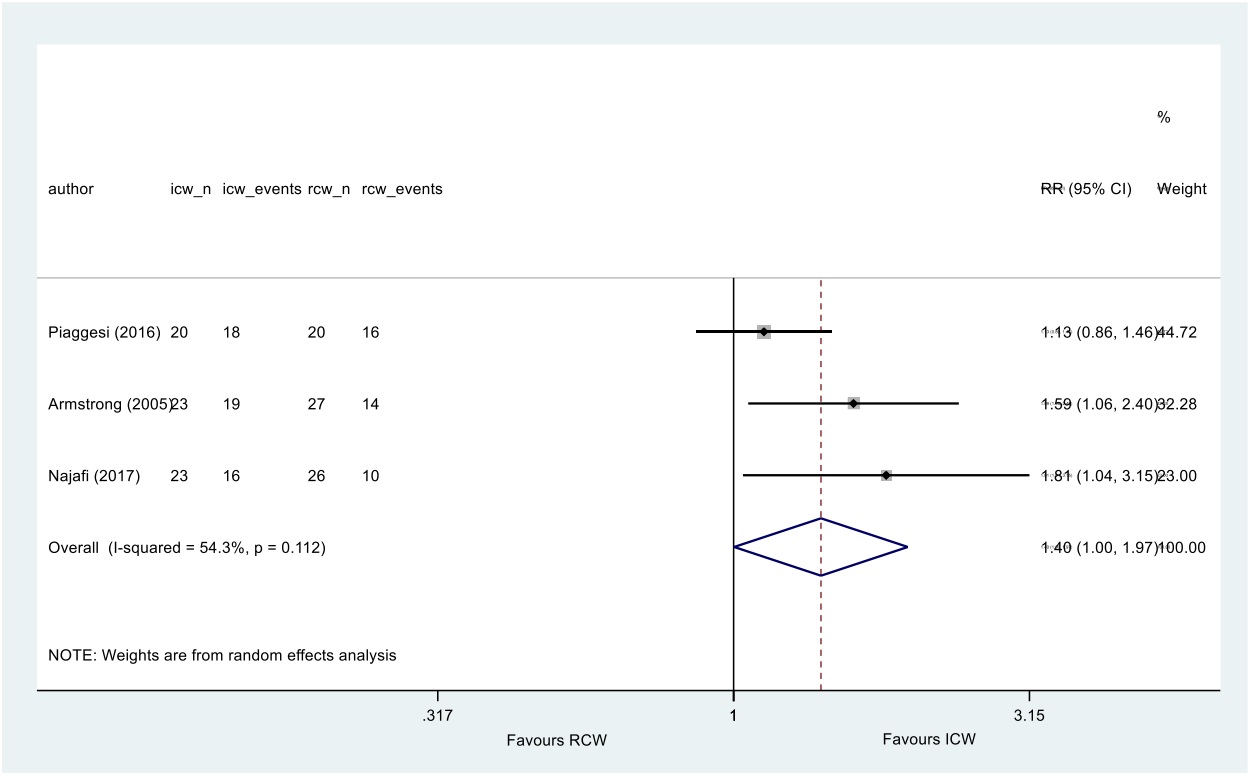


Figure 33. Meta-Analysis ICW vs. RCW Ulcers Healed at 12 Weeks



19.4 **Meta-Analysis Forest Plots: Time to Ulcer Healing**

Figure 34. Meta-Analysis TCC vs. ICW Mean days to Healing

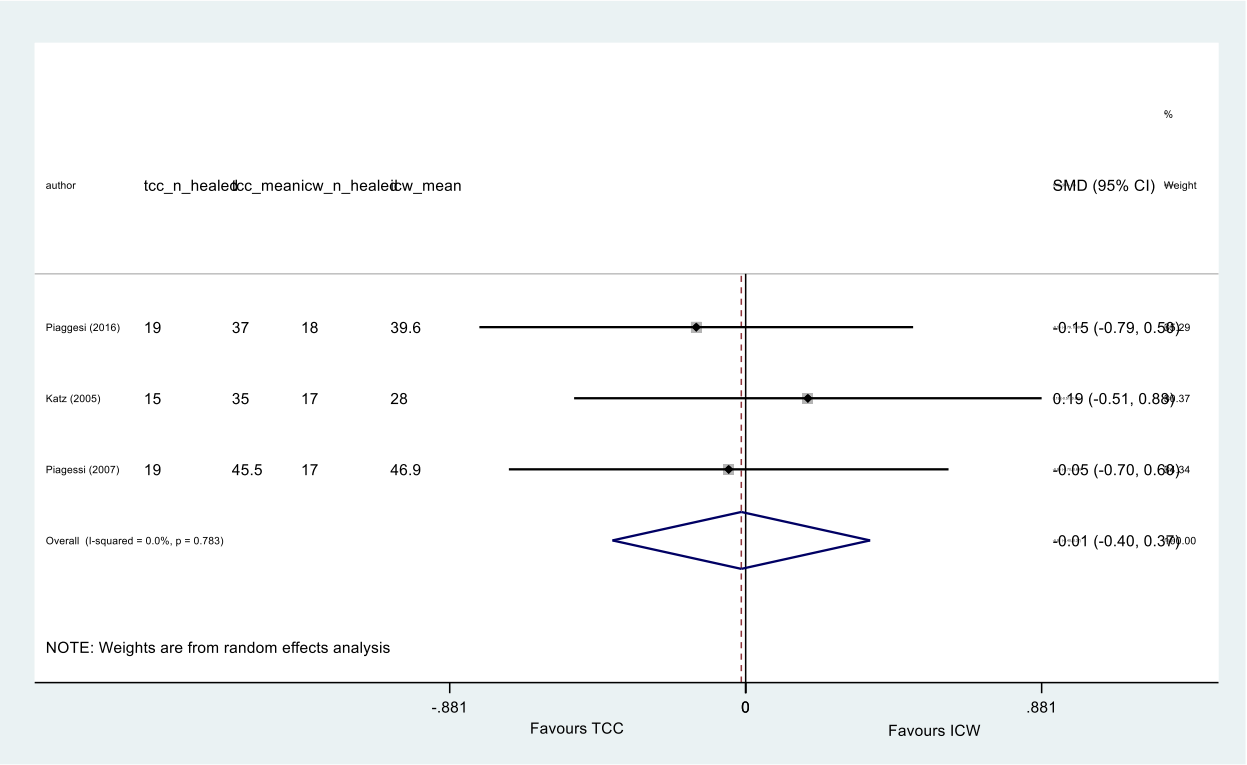


Figure 35. Meta-Analysis TCC vs. RCW Mean Days to Ulcer Healing

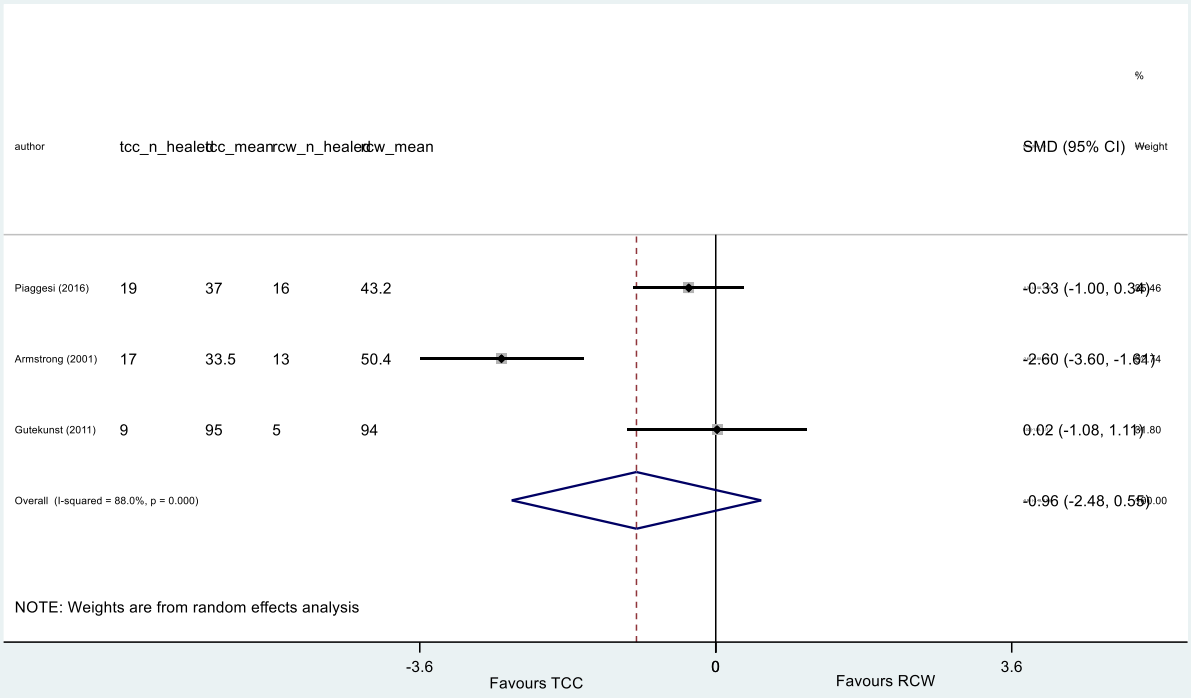
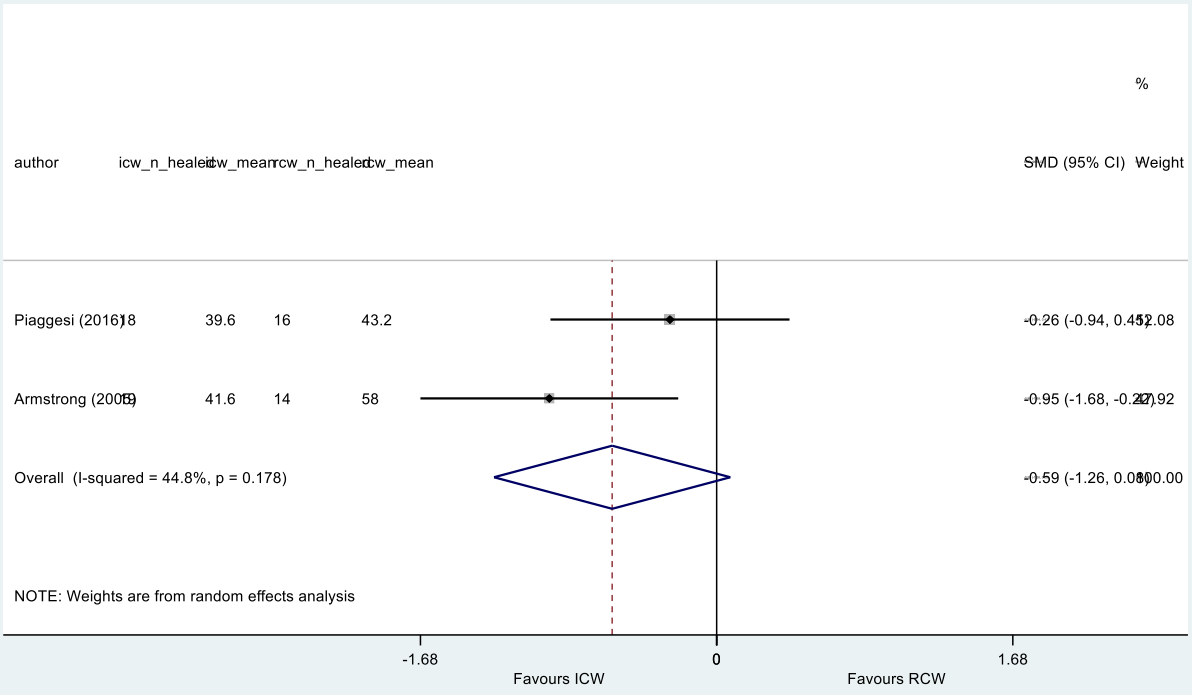


Figure 36. Meta-Analysis ICW vs. RCW for Mean Days to Ulcer Healing



20 Appendix D – Patient Interview Questions

Patient Interview Questions

Patient Experiences with Offloading Devices for Diabetic Foot Ulcers

Patient Interview Guide

Preamble: *As you know, the University of Calgary Health Technology Assessment Unit is speaking with people about their experiences with offloading devices for diabetic foot ulcers as part of the research for a Health Technology Assessment for the BC Ministry of Health. Just so that we are on the same page, I'd like to clarify our definition of "offloading devices". This is the term we use for pressure management devices such as contact casts, removable and irremovable cast walkers, crutches, as well as therapeutic shoes, bed rest, wheelchairs, and so on. We use the term throughout the interview, but if you require clarification at any point, please don't hesitate to ask.*

The interview will take about 60 minutes (depending on your responses) and will be audio-recorded for accuracy. I want to reassure you that your responses will remain confidential and will be anonymous in our reports. I also want to remind you that you may skip a question or stop the interview at any time. Do you have any questions before we begin?

Please ensure that the participant completes the demographic survey prior to participating in the interview.

About you and your experience with diabetic foot ulcers

In this section I'll ask about you and your experience with diabetic foot ulcers.

1. What type of diabetes do you have, and when were you diagnosed?
2. When did you first experience a foot ulcer? What was that like?
3. Approximately how many foot ulcers have you experienced?
4. What is your sense of what caused your foot ulcer?

Your experience with offloading devices

1. Thinking back to your most recent experience with a diabetic foot ulcer… Did your doctor or care provider discuss different options for offloading devices with you? (Probe: For example, were you given a choice between a total contact cast or a removable cast?)

- If yes, which options did you discuss?
    i. Which did you choose, and why?
    ii. Did you have to pay out of pocket for that?
        1. If yes, what was the cost?
            a. What was the financial impact for you? / Was the cost a problem for you?
- How did you get the device? For example, was it available in clinic, or did you have to travel somewhere to get it?
- Did anyone train you on how to use/wear the device?
    i. Did you feel you had adequate instructions on how to use it properly AND/OR follow your doctor's directions?

2. How long (in days, weeks, or months), did you [wear/use] [the device]?
    - What was it like to [wear/use] [*the device*]?
        i. [If not already described] What did it physically feel like?
        ii. What kind of upkeep, adjustments, or maintenance were required? [Probe: For example, how often did you get your contact cast removed and reapplied?]
            1. Did this require driving to the clinic?
            2. How did you typically get to the clinic?
                a. Did that pose a challenge for you?
3. How did using the device impact your daily life? [Probe, only if needed: For example, some patients using casts cannot drive, exercise, or depending on their type of work, attend their jobs]
    - How did not being able to [do that] make you feel?
        i. For rural patients: Living, in [location], how did the inability to drive impact you?
4. What were the biggest challenges you encountered in using [the device]?
    - How did you deal with those challenges?
    - Were there ever moments when you made the decision not to [wear/use] the [device]? [Probe, only if needed: For example, getting up for a quick drink of water in the middle of the night].
        i. [*If yes*] What was your rationale for not using it in that moment?
        ii. What would have made it easier for you to use the device all the time?
5. How did others react to you [wearing/using] the device? For example, did you get any comments from family, friends, or co-workers?
    - [If yes], How did that feel?
    - Did your employer accommodate you at work? If so, how?
6. Thinking about all of these factors, how would you say [wearing/using] [*the device*] affected your quality of life on the whole?
    - Are there any experiences or moments that stand out for you, that you would like to share?

Treatment Process

1. In terms of your treatment and healing, how effective do you feel the [device] was?
    - What was the healing process like?
    - Did you experience any complications?
    - After the device came off, what kind of maintenance was required? For example, orthotics, therapeutic shoes, etc.
        i. How have you found that?
        ii. How consistent are you with wearing/using the shoes/device?
            1. What would make it easier for you?
2. Was anyone else [in addition to your doctor] involved in your care at the clinic? If so, what was their role?
    - Is there anyone in particular who stood out in making a difference to your experience at the clinic?
3. Was anyone else involved in your care at home? If so, what was their role?
    - Is there anyone in particular who stood out in making a difference to your experience at home with the foot ulcer?

Experience with other devices

1. Have you used any other devices in the treatment of your foot ulcer(s)?
   [Same probes for each device]
    - What was it like to use [*the device*]?
    - How did it impact your daily life?
    - What were the biggest challenges you encountered in using [the device]?
2. Thinking about your experiences with different kinds of devices, which would you say you liked most, and why?
3. Thinking big picture, what do you think would make the biggest difference in helping patients like yourself?

Closing questions:

1. If we have questions or issues come up during our analysis, would it be okay to reach out to you by e-mail?
2. Is there anything else you'd like to add?
3. *Ask, if we are having trouble recruiting:* Can you think of anyone else who has used offloading devices who might be interested in sharing their experiences with us?

Thank you so much for your time.

21 Appendix E – Clinician Interview Guide

Clinician Interview Guide

Patient Experiences with Offloading Devices for Diabetic Foot Ulcers

Patient Interview Guide

Preamble: *As you know, the University of Calgary Health Technology Assessment Unit is speaking with people about their experiences with offloading devices for diabetic foot ulcers as part of the research for a Health Technology Assessment for the BC Ministry of Health. Just so that we are on the same page, I'd like to clarify our definition of "offloading devices". This is the term we use for pressure management devices such as contact casts, removable and irremovable cast walkers, crutches, as well as therapeutic shoes, bed rest, wheelchairs, and so on. We use the term throughout the interview, but if you require clarification at any point, please don't hesitate to ask.*

The interview will take about 60 minutes (depending on your responses) and will be audio-recorded for accuracy. I want to reassure you that your responses will remain confidential and will be anonymous in our reports. I also want to remind you that you may skip a question or stop the interview at any time. Do you have any questions before we begin?

About you and your experience with diabetic foot ulcers

In this section I'll ask about you and your experience with diabetic foot ulcers.

5. What type of diabetes do you have, and when were you diagnosed?
6. When did you first experience a foot ulcer? What was that like?
7. Approximately how many foot ulcers have you experienced?
8. What is your sense of what caused your foot ulcer?

Your experience with offloading devices

7. Thinking back to your most recent experience with a diabetic foot ulcer… Did your doctor or care provider discuss different options for offloading devices with you? (Probe: For example, were you given a choice between a total contact cast or a removable cast?)

- If yes, which options did you discuss?
    i. Which did you choose, and why?
    ii. Did you have to pay out of pocket for that?
        1. If yes, what was the cost?
            a. What was the financial impact for you? / Was the cost a problem for you?
- How did you get the device? For example, was it available in clinic, or did you have to travel somewhere to get it?
- Did anyone train you on how to use/wear the device?
    i. Did you feel you had adequate instructions on how to use it properly AND/OR follow your doctor's directions?

8. How long (in days, weeks, or months), did you [wear/use] [the device]?
    - What was it like to [wear/use] [*the device*]?
        i. [If not already described] What did it physically feel like?
        ii. What kind of upkeep, adjustments, or maintenance were required? [Probe: For example, how often did you get your contact cast removed and reapplied?]
            1. Did this require driving to the clinic?
            2. How did you typically get to the clinic?
                a. Did that pose a challenge for you?
9. How did using the device impact your daily life? [Probe, only if needed: For example, some patients using casts cannot drive, exercise, or depending on their type of work, attend their jobs]
    - How did not being able to [do that] make you feel?
        i. For rural patients: Living, in [location], how did the inability to drive impact you?
10. What were the biggest challenges you encountered in using [the device]?
    - How did you deal with those challenges?
    - Were there ever moments when you made the decision not to [wear/use] the [device]? [Probe, only if needed: For example, getting up for a quick drink of water in the middle of the night].

i. [*If yes*] What was your rationale for not using it in that moment?
ii. What would have made it easier for you to use the device all the time?

11. How did others react to you [wearing/using] the device? For example, did you get any comments from family, friends, or co-workers?
    - [If yes], How did that feel?
    - Did your employer accommodate you at work? If so, how?
12. Thinking about all of these factors, how would you say [wearing/using] [*the device*] affected your quality of life on the whole?
    - Are there any experiences or moments that stand out for you, that you would like to share?

Treatment Process

4. In terms of your treatment and healing, how effective do you feel the [device] was?
    - What was the healing process like?
    - Did you experience any complications?
    - After the device came off, what kind of maintenance was required? For example, orthotics, therapeutic shoes, etc.
        i. How have you found that?
        ii. How consistent are you with wearing/using the shoes/device?
            1. What would make it easier for you?
5. Was anyone else [in addition to your doctor] involved in your care at the clinic? If so, what was their role?
    - Is there anyone in particular who stood out in making a difference to your experience at the clinic?
6. Was anyone else involved in your care at home? If so, what was their role?
    - Is there anyone in particular who stood out in making a difference to your experience at home with the foot ulcer?

Experience with other devices

4. Have you used any other devices in the treatment of your foot ulcer(s)?
   [Same probes for each device]
    - What was it like to use [*the device*]?

- How did it impact your daily life?
- What were the biggest challenges you encountered in using [the device]?

5. Thinking about your experiences with different kinds of devices, which would you say you liked most, and why?
6. Thinking big picture, what do you think would make the biggest difference in helping patients like yourself?

Closing questions:

4. If we have questions or issues come up during our analysis, would it be okay to reach out to you by e-mail?
5. Is there anything else you'd like to add?
6. *Ask, if we are having trouble recruiting:* Can you think of anyone else who has used offloading devices who might be interested in sharing their experiences with us?

Thank you so much for your time.

22 Appendix F – Cost-utility analysis health state probability estimates

Figure 37. Health state probability estimates associated with TCC at 4 months, 3 years, and 5 years

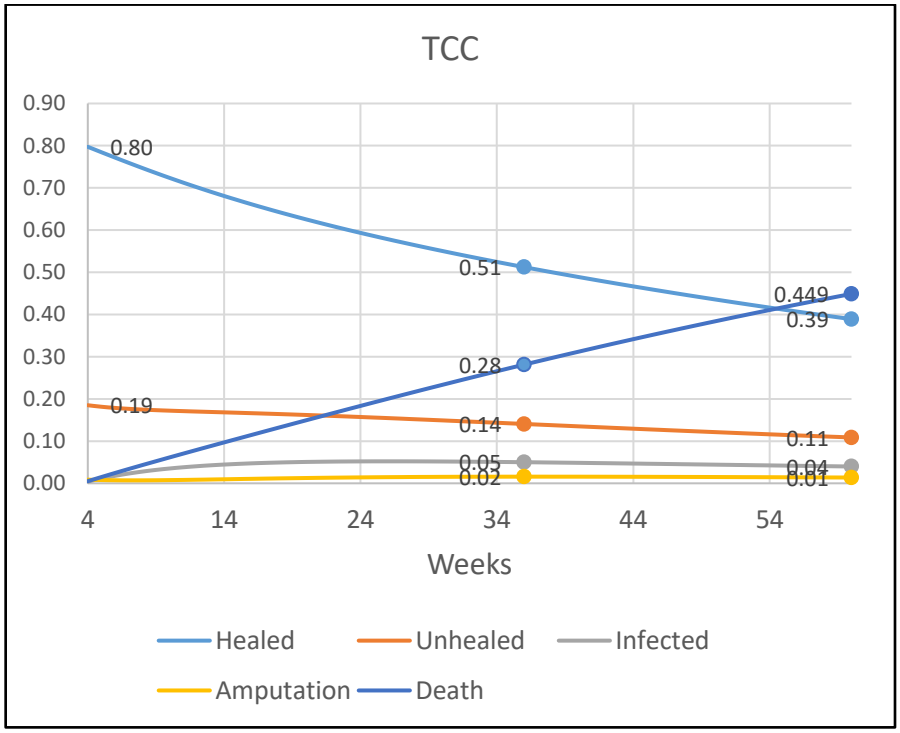


Figure 38. Health state probability estimates associated with ICW treatment at 4 months, 3 years, and 5 years

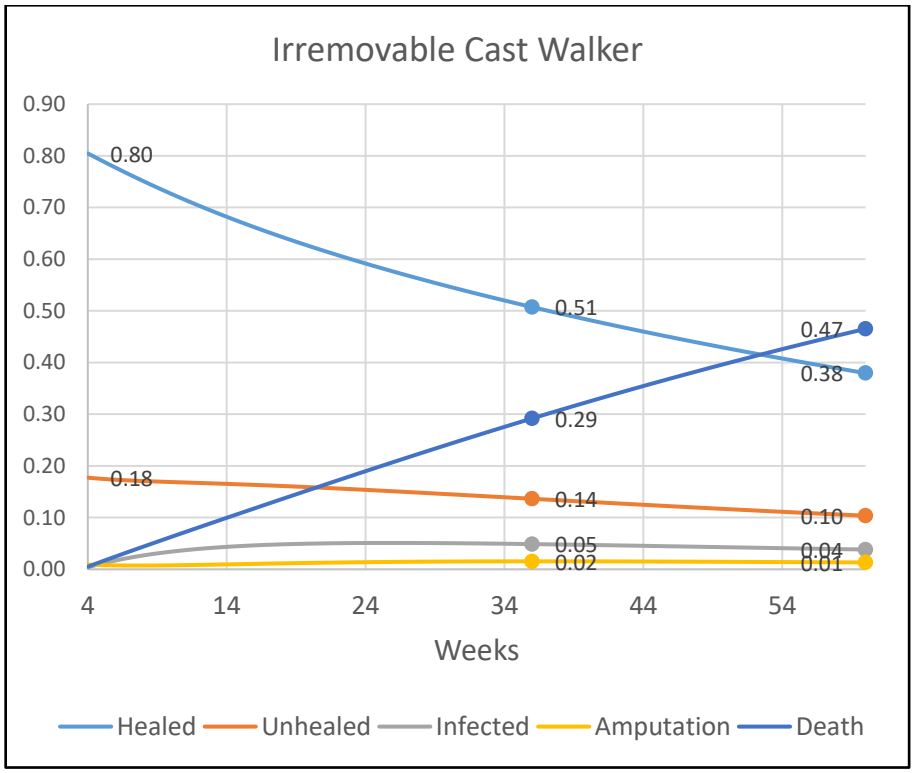


Figure 39. Health state probability estimates associated with RCW treatment at 4 months, 3 years, and 5 years

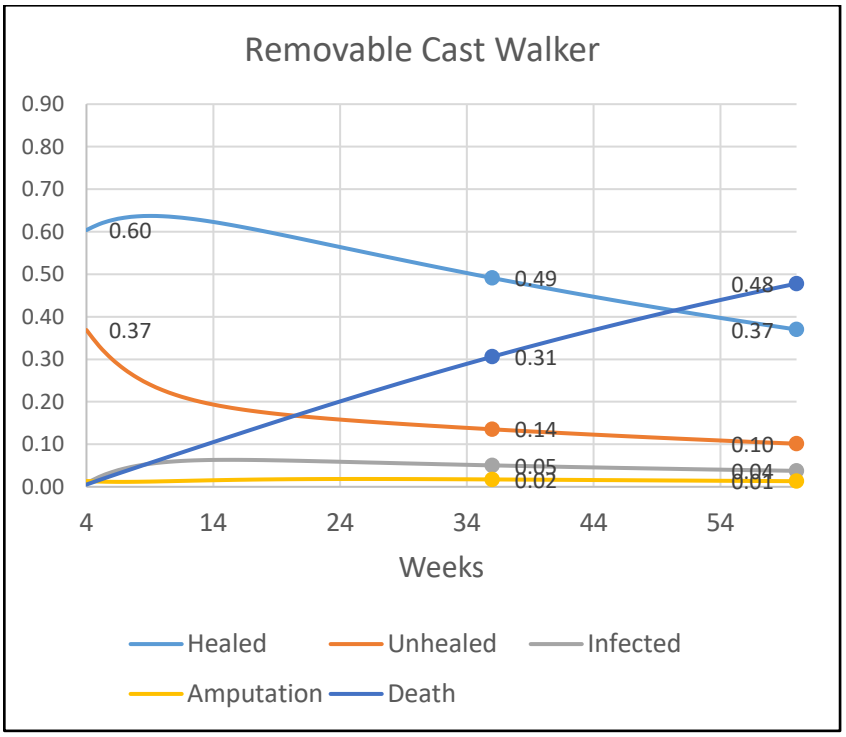
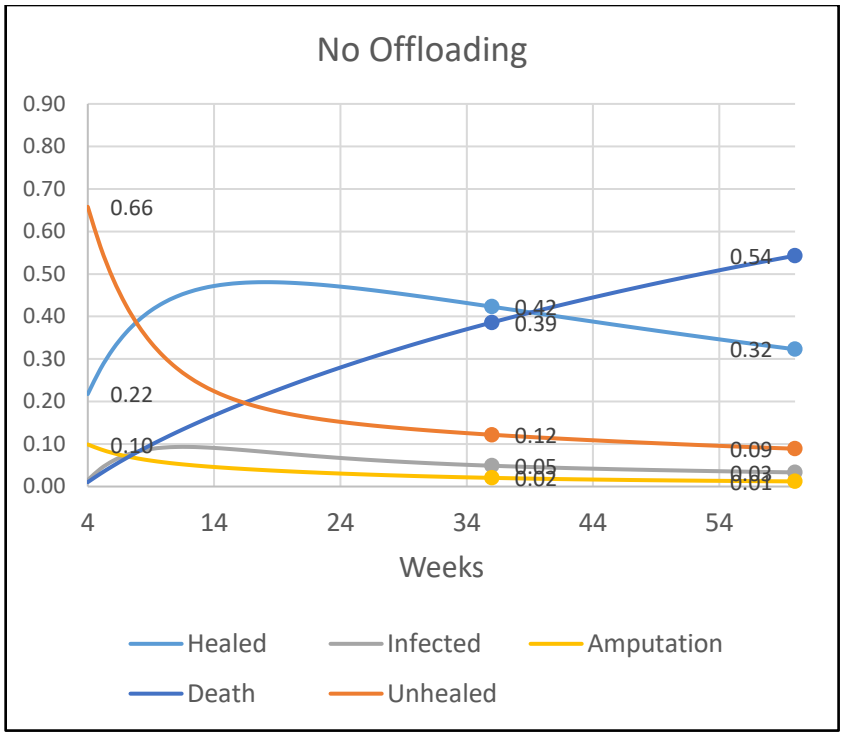


Figure 40. Health state probability estimates associated with no offloading treatment at 4 months, 3 years, and 5 years


No Offloading
0.90
0.80
0.70
0.60
0.50
0.40
0.30
0.20
0.10
0.00
0.66
0.22
0.10
0.54
0.42
0.39
0.32
0.12
0.09
0.05
0.02
0.01
4
14
24
34
44
54
Weeks
Healed
Infected
Amputation
Death
Unhealed

23 Appendix G – Codes Defining BIA Cohort

ICD-10CA Codes Used as Exclusion Criteria:

- Procedure codes for peripheral revascularization:
  - 1KA57LA – Extraction, abdominal aorta, using atherectomy device; no tissue used.
  - 1KA76MZ – Bypass, abdominal aorta, terminating at lower limb vessels, using combined sources of tissue
  - 1KE57LA – Extraction, abdominal arteries NEC, using atherectomy device, using autograft.
  - 1KE76MZ – Bypass, abdominal arteries NEC, terminating in vessels of leg, using combined sources of tissue
  - 1KG57LA – Extraction, arteries of leg NEC, using atherectomy device, using autograft
  - 1KG76MI – Bypass, arteries of leg NEC, terminating in lower limb artery, using synthetic material
  - 1KT57LA – Extraction, vessels of the pelvis, perineum and gluteal region, using atherectomy device, using autograft
  - 1KT76MZ – Bypass, vessels of the pelvis, perineum and gluteal region, terminating in vessels of the leg, using synthetic material
  - 1JM76MI – Bypass, arteries of arm NEC, terminating in lower limb artery, using synthetic material
  - 1KA50GQ – Dilation, abdominal aorta, using percutaneous transluminal approach and balloon dilator with endovascular stent insertion
  - 1KA57GQ – Extraction, abdominal aorta using atherectomy device, using autograft
  - 1KE35 – Pharmacotherapy (local), abdominal arteries NEC
  - 1KE50 – Dilation, abdominal artery NEC
  - 1KE57GQ – Extraction, abdominal arteries NEC, using atherectomy device and percutaneous transluminal approach, no tissue used
  - 1KG35 – Pharmacotherapy (local), arteries of leg NEC
  - 1KG50 – Dilation, arteries of leg NEC
  - 1KG57GQ – Extraction, arteries of leg using atherectomy device and percutaneous transluminal approach, no tissue used
  - 1KT50 – Dilation, vessels of the pelvis, perineum and gluteal region
  - 1KT57GQ – Extraction, vessels of the pelvis, perineum and gluteal region, percutaneous transluminal approach using atherectomy device, no tissue used.
- 170.2 Atherosclerosis of arteries of extremities
- 170.21 – Atherosclerosis of extremities with gangrene
- 173.9 – Peripheral vascular disease, unspecified (includes intermittent claudication)
- E10.50x – Type 1 diabetes mellitus with peripheral angiopathy
- E10.51x – Type 1 diabetes mellitus with peripheral angiopathy with gangrene
- E10.71x – Type 1 diabetes mellitus with foot ulcer (angiopathic)(neuropathic) with gangrene
- E11.51x – Type 2 diabetes mellitus with peripheral angiopathy with gangrene
- E11.71x – Type 2 diabetes mellitus with foot ulcer (angiopathic)(neuropathic) with gangrene

- E13.71x – Other specified diabetes mellitus with foot ulcer (angiopathic)(neuropathic) with gangrene
- E14.50x – Unspecified diabetes mellitus with peripheral angiopathy
- E14.51x – Unspecified diabetes mellitus with peripheral angiopathy with gangrene
- C40.2 – Malignant neoplasm of long bones of lower limb
- C40.3 – Malignant neoplasm short bones of lower limb
- C41.8 – Overlapping malignant lesion of bone and articular cartilage
- C41.9 – Malignant neoplasm bone and articular cartilage, unspecified
- C43.7 – Malignant melanoma of lower limb, including hip
- C47.2 – Malignant neoplasm of peripheral nerves of lower limb, including hip
- C49.2 – Malignant neoplasm of connective and soft tissue of lower limb, including hip
- C76.5 – Malignant neoplasm of lower limb
- C79.5 – Secondary malignant neoplasm of bone and bone marrow
- C90.0 – Multiple myeloma
- C90.20 – Plasmacytoma of bone
- D16.2 – Benign neoplasm of long bones of lower limb
- D16.3 – Benign neoplasm of short bones of lower limb
- D21.2 – Other benign neoplasm of connective and other soft tissue of lower limb, including hip
- C44.7 – Malignant neoplasm skin of lower limb, including hip
- C46.^ - Kaposi's sarcoma
- C47.^ - Malignant neoplasm of peripheral nerves and autonomic nervous system
- D36.1 – Benign neoplasm of peripheral nerves and autonomic nervous system
- S70-79, S80-89, S90-99 – lower extremity trauma
- T01.3^ - open wounds of multiple legions of lower limbs
- T02.3^ - Fractures involving multiple regions of one lower limb
- T02.5^ - Fractures involving multiple regions of both lower limbs
- T04.3-T04.9 – Crush injury including lower limbs
- T05.3-T05.9 – Traumatic amputation including foot or lower limb
- T12.0 – Fracture of lower limb, level unspecified, closed
- T13.0 – Superficial injury of lower limb, level unspecified
- T13.1 – Open wound of lower limb, level unspecified
- T13.2 – Dislocation, sprain and strain of unspecified joint and ligament of lower limb, level unspecified
- T13.3 – Injury of unspecified nerve of lower limb, level unspecified
- T13.4 – Injury of unspecified blood vessel of lower limb, level unspecified
- T13.5 – Injury of unspecified muscle and tendon of lower limb, level unspecified
- T13.6 – Traumatic amputation of lower limb, level unspecified
- T13.8 – Other specified injuries of lower limb, level unspecified
- T13.9 – Unspecified injury of lower limb, level unspecified
- T24.0 – Burn of unspecified degree of hip and lower limb, except ankly and foot

- T24.1 – Burn of first degree of hip and lower limb, except ankle and foot
- T24.2 – Burn of second degree of hip and lower limb, except ankle and foot
- T24.3 – Burn of third degree of hip and lower limb, except ankle and foot
- T24.4 – Corrosion of unspecified degree of hip and lower limb, except ankle and foot
- T24.5 – Corrosion of first degree of hip and lower limb, except ankle and foot
- T24.6 – Corrosion of second degree of hip and lower limb, except ankle and foot
- T24.7 – Corrosion of third degree of hip and lower limb, except ankle and foot
- T25.0 – Burn of unspecified degree of ankle and foot
- T25.1 – Burn of first degree of ankle and foot
- T25.2 – Burn of second degree of ankle and foot
- T25.3 – Burn of third degree of ankle and foot
- T25.4 – Corrosion of unspecified degree of ankle and foot
- T25.6 – Corrosion of second degree of ankle and foot
- T25.7 – Corrosion of third degree of ankle and foot
- T33.^ - Frostbite
- T24.^ - Frostbite with necrosis
- T35.^ - Frostbite unspecified
- T79.6 – Traumatic ischemia of muscle
- M12.55 – Traumatic arthropathy, pelvic region and thigh
- M12.56 – Traumatic arthropathy, lower leg
- M12.57 – Traumatic arthropathy, ankle and foot
- M12.58 – Traumatic arthropathy, other site
- M12.59 – Traumatic arthropathy, unspecified site
- T84.54 – Infection and inflammatory reaction due to knee prosthesis
- T84.^ - Complications of internal orthopaedic prosthetic devices, implants and grafts (hip prosthesis, knee prosthesis, internal fixation device of bones of limb, infection and inflammatory reaction due to internal joint prosthesis, Infection and inflammatory reaction due to internal fixation device [any site])
- L89.^ - decubitus ulcer
- M84.^ - Disorders of continuity of bone (malunion, nonunion, delayed union) of fracture
- M96.6^ - Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plat3e
- Q27.8 – Other specified congenital malformations of peripheral vascular system
- Q27.9 – Congenital malformation of peripheral vascular system, unspecified – Anomaly of artery or vein not otherwise specified
- Q65.^ - Congenital deformities of hip
- Q66.^ - Congenital deformities of feet
- Q68.2^ - Congenital deformity of knee
- Q68.3^ Congenital bowing of femur
- Q68.4^ Congenital bowing of tibia and fibula
- Q68.5 – Congenital bowing of long bones of leg, unspecified

- I83.^ - Venous ulcer
- I87.2 – Venous insufficiency (chronic)(peripheral)

I89.0 Lymphoedema, not elsewhere classified