IMPACT OF OFFLOADING DEVICES ON THE COST OF DIABETIC FOOT ULCERS IN ONTARIO
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About this Study

This report was commissioned by the Canadian Diabetes Association to assess the potential impact of public funding for offloading devices on the cost of care for diabetic foot ulcers in Ontario. Diabetic foot ulcers are common and debilitating and are considered by people with diabetes to be the most feared and debilitating consequences of diabetes. Indeed, foot complications, including infections, ulcerations and amputations, are a major cause of morbidity and mortality in people with diabetes. Furthermore, foot complications impose significant costs on the healthcare system in Ontario. These costs can, in part, be mitigated through the increased use of offloading devices to treat foot ulcers.

The Canadian Diabetes Association (CDA) is a leading national and international authority on diabetes. The CDA has a rich heritage of excellence and leadership, which began with its co-founders and the co-discoverers of insulin, Drs. Frederick Banting and Charles Best. The CDA delivers programs and services for people affected by diabetes, funds leading-edge research and produces globally recognized diabetes clinical practice guidelines. The Association works in communities across the country to promote the health of people with diabetes and to reduce the complications of diabetes through its national network of volunteers, employees, health care professionals, researchers, partners and supporters. For more information please go to www.diabetes.ca.

The report was prepared by Robin Somerville, Director, of the Centre for Spatial Economics (C4SE) and Seema Nagpal, Director of Public Policy, Canadian Diabetes Association. The C4SE monitors, analyzes and forecasts economic and demographic change throughout Canada at virtually all levels of geography. It also prepares customized studies on the economic, industrial and community impacts of various fiscal and other policy changes, and develops customized impact and projection models for in-house client use. The C4SE provides economic models, analysis and forecasts to nine provincial and territorial governments across Canada. For more information please go to www.c4se.com.

The authors are grateful to Dr. John Embil, Director, Infection Prevention and Control Unit, Coordinator, Diabetic Foot and Complicated Wound Clinic, Health Sciences Centre and Professor, Departments of Internal Medicine, (Section of Infectious Diseases) and Medical Microbiology, University of Manitoba for providing his clinical expertise into the analysis for reviewing a draft of this report.
Executive Summary

Diabetic foot ulcers (DFU) currently impose direct health care costs of between $320 and $400 million in Ontario and indirect costs of between $35 and $60 million. Provincial funding of offloading devices could yield net direct cost savings of between $48 and $75 million: a reduction of between 12 and 23% over 1 year. In addition to the economic burden on public funders of health care, diabetes has a significant impact on disability and quality of life.1234

The analysis in this report is based on a model constructed to estimate the prevalence and cost of DFU in Ontario in 2015 and the impact that the use of offloading devices in their treatment could have on those costs and health outcomes.

Foot complications, including infections, ulcerations and amputations, are a major cause of morbidity and mortality in people with diabetes. In Canada, diabetes is the leading cause of non-traumatic lower limb amputations. Diabetes-related foot wounds contributed to about one-third of all amputations performed in hospitals across Canada in 2011-12. The mortality rate for people experiencing diabetic foot complications is worse than rates of some forms of cancer; in fact, the 5-year mortality rate for those with a neuropathic ulcer is higher than that of Hodgkin’s disease, breast cancer or prostate cancer; and those with ischemic ulcer have a 5-year mortality higher than those with colon cancer. Effective treatment of foot ulcers may be associated with significant cost savings to the health care system.

The risk of an amputation increases dramatically once an ulcer appears but effective treatment of the ulcer with an offloading device can reduce this risk. Offloading devices used in the treatment of DFUs vary in cost and effectiveness. Total contact casts (TCC) and custom braces, ankle and foot orthoses significantly improve patient outcomes but are not widely used due to issues of affordability. Provincial funding of offloading devices for the treatment of DFU in Ontario is expected to significantly increase their use by patients in the province and to improve their health outcomes.

Of the 1.53 million people with diabetes in Ontario, between 16,600 and 27,600 are expected to have a DFU in 2015. Of these, nearly 2,000 are expected to need to have a lower limb amputated as a result of their condition and those amputations are associated with almost 800 premature deaths. The use of offloading devices can significantly reduce the number of amputations, allow wounds to heal faster and with a lower risk of complications. All these factors combine to significantly reduce the overall cost of DFUs in Ontario and their toll on Ontarians.
Introduction

Diabetes is a condition characterised by an elevation in blood glucose (blood sugar) levels due to either a lack of insulin or a reduced effectiveness of one’s own insulin. This leads to high levels of glucose in the blood, which can damage organs, blood vessels and nerves. Diabetes is a leading cause of blindness, end-stage renal disease, heart disease, stroke and non-traumatic amputation in Canadian adults. Persons diagnosed with diabetes can be classified as having type 1, type 2, gestational or prediabetes.

The authors of this report acknowledge the human toll that complications of diabetes, particularly lower extremity complications can impose upon persons with diabetes. The fear of complications, and the emotional strain of the non-healing ulcer and/or amputation places an enormous burden on individuals and their families. However, this report will exclusively focus on the cost implications of treating diabetic foot ulcers (DFU) by increasing the use of offloading devices to treat the foot ulcers in Ontario.

Foot complications, including infections, ulcerations and amputations, are a major cause of morbidity and mortality in people with diabetes. In Canada, diabetes is the leading cause of non-traumatic lower limb amputations. Diabetes-related foot wounds contributed to about one-third of all amputations performed in hospitals across Canada in 2011-12. The mortality rate for people experiencing diabetic foot complications is worse than rates of some forms of cancer; in fact, the 5-year mortality rate for those with a neuropathic ulcer is higher than that of Hodgkin’s disease, breast cancer or prostate cancer; and those with ischemic ulcer have a 5-year mortality higher than those with colon cancer. Effective treatment of foot ulcers may be associated with significant cost saving to the health care system.

Offloading devices used in the treatment of DFUs vary in cost and effectiveness with the least expensive being the least effective. Total contact casts (TCC) and custom braces, ankle and foot orthoses significantly improve patient outcomes but cost about $2,000 and so are not widely used due to issues of affordability. Provincial funding of offloading devices for the treatment of diabetic foot ulcers (DFU) in Ontario would significantly increase their use by patients in the province and improve their health outcomes. This report examines the costs of provincial funding, describing both the cost of offloading devices as well as the cost savings from avoided health services. The overall healthcare costs and health benefits arising from access to publicly funded offloading devices are estimated. The costs are calculated from both a payer and a societal perspective.

The analysis for this report was conducted using a model of the prevalence and cost of DFUs in Ontario in 2015 constructed by the C4SE. The model examined the cost implication of increasing the proportion of patients using an offloading device to treat their DFU based on a set of assumptions regarding the prevalence of DFUs in the province.

Diabetes in Ontario

The number of people with diabetes in Ontario is estimated to be 1.53 million in 2015 with the distribution by age and sex shown in Figure 1. More males have diabetes than females (52% of the total)
and the largest group of persons with diabetes is between the ages of 65 and 69. The estimated prevalence of diabetes is derived from the CDA’s Diabetes Cost Model for Ontario.\textsuperscript{5}
Model Assumptions

A model was constructed to estimate the number of persons with DFUs in Ontario in 2015 and their health outcomes based whether or not they used an offloading device. A set of estimates for the cost of treating DFUs was then constructed based on the health outcomes under each set of assumptions for the use of offloading devices. This section of the report describes the assumptions and data used to construct the model.

DFU Cost Model

Figure 2 provides an overview of the diabetic foot ulcers (DFU) cost model structure. The prevalence of DFUs by age and sex are determined by the prevalence of diabetes in Ontario in 2015 and by the assumed lifetime probability of a DFU for persons with diabetes. Health outcomes for the population of patients with a DFU are determined by the number of persons with a DFU and the likelihood of each outcome. Treatment costs and societal costs per patient are multiplied by the health care requirements for each health outcome and the number of patients for each health outcome to determine total costs. The total cost of DFUs varies with the proportion of patients assumed to use an offloading device in their treatment because of differences in health outcomes, per patient costs, and health care requirements by outcome that arise when these devices are used.

DFU Prevalence and Outcome Estimates

The prevalence of DFU in Ontario is estimated based on three possible scenarios where the lifetime probability of a person with diabetes developing a DFU varies from 15 to 25%. The distribution of DFU by age and sex is based on the national distribution estimated by Hopkins et al.6 combined with the
Ontario DM prevalence estimates for 2015 and varies between 16,600 and 27,600. These figures are shown in the Simulation 1, Simulation 2, and Simulation 3 rows in Table 1.

There will be an estimated 1,954 amputations related to DFUs in Ontario in 2015. This estimate is derived from the 1,970* lower limb amputations performed in Ontario in 2012 on persons with diabetes. The 2012 amputations were adjusted by the 2015 diabetes rate and then adjusted for the estimated to the proportion of all amputations in people with diabetes that are the result of a non-healing DFU (85%)7. These 1,954 amputations related to non-healing DFUs were held constant and resulted in an amputation rate of between 7.1% and 11.8% for the three model simulations.

A recent study by Hopkins et al estimates the national burden of illness in Canada for diabetic foot ulcer (DFU) for 2011. They found the national prevalence of DFU to be 25,600 in 2011 but acknowledge that this likely underestimates the true prevalence given that the estimate is based on data that exclude DFUs treated outside of acute care facilities. Applying their age and sex DFU prevalence rates and their estimated amputation rate (23.6%) to Ontario’s diabetes population yields a prevalent population of 12,077 DFU cases in the province and 2,848 amputations in 2015. Alternatively, Fife estimates the amputation rate for non-healing DFUs is between 2 and 10%. Holding the number of amputations in Ontario constant (n= 1,954 amputations), the estimate for the number of DFUs in Ontario is between 19,544 and 97,720. There is a large variation in these estimates, emphasizing the need for more population-based research to develop more accurate estimates of the prevalence of DFUs, their complications and the likelihood of an amputation. For the present analysis, a range of estimates are used to describe the impact of public funding of offloading devices.

<table>
<thead>
<tr>
<th>DFU Prevalence in Ontario</th>
<th>Pr(DFU)</th>
<th># DFU</th>
<th>Amp Rate</th>
<th># Amp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hopkins et al.</td>
<td>15%</td>
<td>12,077</td>
<td>23.6%</td>
<td>2,848</td>
</tr>
<tr>
<td>Sim1</td>
<td>15%</td>
<td>16,563</td>
<td>11.8%</td>
<td>1,954</td>
</tr>
<tr>
<td>Sim2</td>
<td>20%</td>
<td>22,084</td>
<td>8.9%</td>
<td>1,954</td>
</tr>
<tr>
<td>Sim3</td>
<td>25%</td>
<td>27,604</td>
<td>7.1%</td>
<td>1,954</td>
</tr>
<tr>
<td>Fife - low</td>
<td></td>
<td>19,544</td>
<td>10.0%</td>
<td>1,954</td>
</tr>
<tr>
<td>Fife - med</td>
<td></td>
<td>39,088</td>
<td>5.0%</td>
<td>1,954</td>
</tr>
<tr>
<td>Fife - high</td>
<td></td>
<td>97,720</td>
<td>2.0%</td>
<td>1,954</td>
</tr>
</tbody>
</table>

Once a patient has a DFU it can either heal without complication, heal with complications or require a lower limb amputation. If the patient requires an amputation, it can either heal normally, heal with complications or result in the patient’s death. The following section provides a discussion of the probability associated with each of these events and the impact that offloading devices can have on each outcome.

* Hospital separation data in Ontario were obtained to determine the number of amputations performed on people with diabetes in 2012.
Probability DFU heals: the probability that a DFU heals without complications without the aid of an offloading device is assumed to be 31%.

This probability rises to 64% when an offloading device is used based on the effectiveness of each device and the proportion in which they are assumed to be used.

Probability DFU heals with complications: the probability of the wound healing with complications for both cases when an offloading device is used or not is treated as the residual from healing without complications and amputation.

Probability of amputation: Fife estimates the probability of an amputation when an offloading device is used is expected to be between 1.5 and 5%. The upper figure of 5% was used in order to ensure that the results could be considered conservative. The probability of an amputation when no offloading device is used varies depending on the assumed lifetime probability of a person with diabetes developing a DFU: at 25% it is 7.1%, at 20% it is 8.9%, and at 15% it is 11.8% (see Table 1). The varying rates of amputation ensure that the number of amputations associated with a DFU in Ontario in 2015 when no offloading devices is held constant at 1,954.

Probability amputation heals: this is residual and, based on assumptions about the proportion of complications and deaths following amputation. This is 50% when no offloading device is used but is lower when an offloading device is used to adjust the number of premature deaths attributed to DFUs.

Probability amputation heals with complications: this is assumed to be 10%. The range of outcomes provided by experts was between 5 and 10%.

Probability of death following amputation: this is assumed to be 40% when no offloading device is used but is higher when an offloading device is used to adjust the number of premature deaths attributed to DFUs. The rate of mortality after 1 year is estimated to be between 20 and 40% rising to between 60 and 80% at 5 years.
Figure 3 shows the distribution of DFUs in 2015 by age and sex based on the assumption of a 15% lifetime probability of a DFU and zero percent of patients using an offloading device. Figure 3 also shows the number of amputations and deaths associated with DFUs by age and sex. Males account for nearly two thirds of all DFUs and although DFUs can occur in patients in their 20s, over 60% arise between the ages of 55 and 80.

**Unit Cost Estimates**

The unit cost estimates or assumptions are the costs per patient associated with each health outcome from a DFU. Many of the unit cost values were derived from the Economic Burden of Illness in Canada (EBIC)\(^\text{12}\) while others were derived from the analysis performed by Hopkins et al.

**Physician visits**: the cost per visit to a physician (GP or specialist) is estimated from EBIC. The Ontario cost by age and sex was divided by the net number of physician visits by persons with diabetes in the same year from the DCM. The average cost between 2006 and 2008 by age and sex, measured in 2010 dollars, was used and then converted to 2015 dollars.

**Hospital days**: the average cost per hospital day associated with DFU in Canada was estimated to be $980 in 2011 by Hopkins et al. This value was converted to 2015 dollars.

**Long-term care**: the average cost per person for long-term care for both new and current residents was obtained from Hopkins et al and, when converted to 2015 dollars, is $18,900. The use of an offloading device does not directly affect the likelihood requiring long-term care or its cost; so this cost category is unaffected by the use of offloading devices.
**Home care:** the average cost per person for home care was obtained from Hopkins et al and, when converted to 2015 dollars, is $10,600. It should be noted that the home care costs used in this analysis exclude informal caregiver costs. In Hopkins et al, caregiver costs for home care are based on a value of time spent by relatives or other unpaid persons providing care for the patient. These costs are not used in this analysis because this category of costs are not currently included in the EBIC methodology for indirect costs.

The use of offloading devices reduces the requirement for home care and, therefore, the average per patient cost of home care. Total contact casts and cast shoes eliminate the need for home care; a pneumatic air cast reduces the duration of home care by 50% while a post-operative shoe reduces it by 10%. The weighted average reduction in per patient costs when using an offloading device and when the DFU heals is 76%. There is no change in the need for home care if the patient requires an amputation, with or without the prior use of an off-loading device.

**Disability:** the morbidity costs are estimated from EBIC. The national cost by age and sex was divided by the number of persons with diabetes in the same year from the DCM adjusted by the loss of productivity for that age and sex group derived from the Loss of Productivity module in the Canadian Community Health Survey (CCHS) public use microdata file for the 2011-12 cycle. Morbidity costs in EBIC represent the potential lost production in the economy from illness and are assumed to exist for as long as it takes the worker to return to work or for them to be replaced. The costs associated with those not in the labour force – for reasons of age or other personal circumstances – are assumed to be zero. The average cost between 2006 and 2010 by age and sex, measured in 2010 dollars, was used and then converted to 2015 dollars.

**Mortality:** the cost of premature mortality is estimated from EBIC. The Ontario cost by age and sex was divided by the number of persons with diabetes that died in the same year from the DCM. Mortality costs in EBIC represent the potential lost production in the economy from premature mortality and are assumed to exist for as long as it takes to replace a deceased worker. The costs associated with those not in the labour force – for reasons of age or other personal circumstances – are assumed to be zero. The average cost between 2006 and 2008 by age and sex, measured in 2010 dollars, was used and then converted to 2015 dollars.

**Offloading device:** While orthopedic foot wear and custom molded orthotics are considered an option by some clinicians, we assumed those off-loading devices were modalities reserved for patients whose ulcers heal as a means to prevent recurrence. Offloading devices were assumed to be used in the following proportions with average costs (measured in 2012 US dollars) based on Alavi et al:

- **Total contact cast**: 40% $1,800
- **Air walking cast**: 30% $300
- **Custom braces, ankle and foot orthoses**: 20% $2,500
- **Post-operative shoe**: 10% $75
Using this information, the weighted average cost for an offloading device, expressed in 2015 Canadian dollars, is $1,425. The cost of orthotist visits is added to this based on: eight visits for a total contact cast, one for an air walking cast, three for custom braces, ankle and foot orthoses, and none for a post-operative shoe for an average of 4.1 visits for all offloading devices.

Total Cost Estimates

The unit cost estimates are multiplied by the number of persons with a DFU based on their health outcome and their use of an offloading device to generate an estimate of the total cost of the illness.

**Physician visits:** the cost of physician visits is determined by the number of DFU patients by outcome times the average cost per visit times the number of visits associated with each outcome. The number of physician visits within one year for a patient with a DFU that heals normally is assumed to be 12 with no offloading device and this falls to 6 physician visits when an offloading device is used. Twenty physician visits are required for a DFU that heals with complications when no offloading device is used and this falls to 12 physician visits when an offloading device is used. Four physician visits are required for an amputation that heals normally and 8 physician visits are required for an amputation that heals with complications.

**Hospital days:** the cost of hospital care is determined by the number of DFU patients by outcome times the average cost per visit times the number of days associated with each outcome. The average number of days spent as an inpatient in hospital when the DFU heals normally is 3.1 plus an average of another 1.8 days for ER and clinic visits. The number of days spent in hospital rises to 6.7 when there are complications plus 1.8 days for ER and clinic visits. The number of days spent in hospital when the patient must have a lower limb is amputated is 71.9 plus 1.8 days for ER and clinic visits and a further 12 days for rehab clinic visits. Hopkins et al estimate that the average cost of ER, clinic and rehab clinic visits is 20% of the inpatient hospital day.

**Long-term care:** Hopkins et al estimate that 14% of DFU patients require long-term care. This proportion is multiplied by the average cost per patient and the number of patients to determine the total cost. The use of an offloading device does not affect these costs.

**Home care:** Hopkins et al estimate that 22% of DFU patients require home care. This proportion is multiplied by the average cost per patient and the number of patients to determine the total cost. As discussed above, the use of offloading devices reduces the requirement for home care by 76% for patients with a DFU that heals but there is no reduction in the need for home care if the patient requires an amputation.

**Disability:** the disability cost is determined multiplying all persons with a DFU that either avoid an amputation or survive it times their per person morbidity cost by age and sex from EBIC. Average morbidity costs for persons with DFUs that heal normally are assumed to be one half of those for all other persons.
Mortality: the mortality cost is determined by the number of patients that die within a year of an amputation or from complications due to diabetes by age and sex times their per person mortality cost from EBIC.

Offloading device: the cost of offloading devices is determined by the number of DFU patients that use a device times the average cost of a device.
Results

This section of the report presents the impact on costs of DFUs in Ontario in 2015 from an increase in the use of offloading devices to treat foot ulcers. Direct costs include hospital costs, physician visits, long-term care and home care. Indirect costs include morbidity and premature mortality costs. Total costs from a payer perspective are the sum of direct costs and the cost of offloading devices; adding indirect costs yields the cost from a societal perspective.

Table 2 provides information on the overall prevalence of DFUs and the number of amputations and premature deaths that can be attributed to them for three scenarios in which the lifetime probability of a person with diabetes suffering from a DFU varies from 15% to 25%. The number of amputations, premature deaths, and the costs of treatment vary based on the proportion of persons using an offloading device to treat their DFU. This proportion is varied from 0% to 75% for each of the three scenarios.

As discussed in the previous section, the estimated number of DFUs varies between 16,600 and 27,600 for each of the three scenarios. When the proportion of persons using an offloading device is zero, the number of amputations is 1,950 leading to 780 premature deaths. If 75% of patients with a DFU use an offloading device in their treatment then the number of amputations falls to between 1,110 and 1,520 depending on the scenario. Unfortunately, while the number of amputations falls the number of premature deaths from DFUs remains constant regardless of whether an amputation is avoided due to the use of an offloading device. This is due to the severity of damage to the vascular system that precipitated the DFU. Action to reduce the incidence of DFUs will be required to reduce premature mortality.

The overall cost of DFUs - direct plus indirect and the cost of offloading devices - is estimated to be between $358 million and $456 million when no offloading devices are used. When 75% of patients use
an offloading device to treat their DFU, the overall cost falls to between $278 million and $399 million a year.

Table 2 also shows that the average cost in 2015 is estimated to lie between $16,500 and $21,640 per DFU when no offloading devices are used. When 75% of patients used an offloading device to treat their DFU, the average cost falls to between $14,450 and $16,780.

Table 3 presents the results in terms of the impact of increasing the proportion of persons using an offloading device to treat their DFU for each of the three scenarios. The table shows the impact of increasing the proportion of patients using an offloading device from zero to 25%; 25% to 50%; 50% to 75%; and from zero to 75%.

The number of persons with a DFU is not affected by the increased use of offloading devices; improvements in diabetes management, screening and footcare are needed to reduce the prevalence of DFUs. However, increasing the proportion of persons using an offloading device by 25% reduces the number of lower limb amputations by between 144 and 282 depending on the lifetime probability of suffering from a DFU.

The improvement in patient outcomes reduces the total cost of DFUs by between $19 and $27 million in 2015 for each 25% increase in the use of offloading devices. Direct costs fall between $27 million and $32 million but are partially offset by spending of between $7 and $11 million on offloading devices. The estimated reduction in indirect costs from morbidity and premature mortality with each 25% increase in use is between $1.8 and $3.0 million in 2015.

In summary, provincial funding of offloading devices is likely to increase the use of these devices to up to 75% of patients with DFUs. Offloading devices cost an average of $1,425 per person plus the cost of orthotist visits for a total of between $20 and $34 million a year. Other associated direct healthcare costs are, however, expected to fall by between $2,970 and $5,770 per DFU for a total reduction of between $82 and $96 million a year yielding a substantial net saving for the government of between $48 and $75 million a year: a reduction of between 12 and 23% over 1 year. Indirect costs from morbidity...
and premature mortality are expected to fall also by about $300 per DFU for a total of between $5 and $9 million.

The results of this analysis address cost implications of public funding for offloading devices for healing DFU, but other issues remain. **Strategies on how to prevent relapses of ulceration after the ulcer has closed, including the use of orthotics and orthopaedic foot wear as well as ongoing maintenance foot care should be explored.** Equally important is the prevention of initial ulceration through self-foot checks and regular foot care from health professionals. Further work needs to be completed to describe the cost-effectiveness for these interventions in Ontario. These issues are extremely important but were beyond the scope of the present analysis.
References


