



Prevention of Diabetic Foot Ulcers: The Role of Telemedicine and Technology

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Outline

- **The Burden of Diabetes**
- **Telemedicine**
 - Diabetes
 - Diabetic Foot Ulcers (DFU)
- **Technology**
 - Remote Temperature Monitoring (RTM)
- **Retrospective Review of a Regional Health Plan with RTM Program in High-Risk Dual Eligible and Medicaid Patients**
 - Outcomes
 - Satisfaction
 - Fall-risk findings

POLL QUESTION

What are we trying to prevent?

- **11%** Americans (**38 million**) have diabetes
- **20%** Hospital admissions
- **20%** of people who develop a diabetic foot infection (DFI) will require an amputation
- **33%** CMS spending on diabetes related complications
(**15 billion annually** on DFU)
- **34%** Risk of developing a DFU
- **47%** Mortality at **5 years** after an amputation
- **50%** Hispanic and African American children born since 2000 will develop diabetes
- Blacks are **4x more likely** to undergo amputation

Every 5 minutes in the US, 2 people die of diabetes-related causes and 14 adults are newly diagnosed

What are we trying to prevent?



- **Ulceration**
- **Infection**
- **Hospitalization**
- **Amputation**
- **Excess Spending**
- **Impaired Quality of Life**

Prevention of Foot Ulcers

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2016; 32(Suppl. 1): 195–200.

Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/dmrr.2738

SUPPLEMENT ARTICLE

A shift in priority in diabetic foot care and research: 75% of foot ulcers are preventable

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Abstract

Diabetic foot ulceration poses a heavy burden on the patient and the healthcare system, but prevention thereof receives little attention. For every euro spent on ulcer prevention, ten are spent on ulcer healing, and for every randomized controlled trial conducted on prevention, ten are conducted on healing. In this article, we argue that a shift in priorities is needed. For the prevention of a first foot ulcer, we need more insight into the effect of interventions and practices already applied globally in many settings. This requires systematic recording of interventions and outcomes, and well-designed randomized controlled trials that include analysis of cost-effectiveness. After healing of a foot ulcer, the risk of recurrence is high. For the prevention of a recurrent foot ulcer, home monitoring of foot temperature, pressure-relieving therapeutic footwear, and certain surgical interventions prove to be effective. The median effect size found in a total of 23 studies on these interventions is large, over 60%, and further increases when patients are adherent to treatment. These interventions should be investigated for efficacy as a state-of-the-art integrated foot care approach, where attempts are made to assure treatment adherence. Effect sizes of 75–80% may be expected. If such state-of-the-art integrated foot care is implemented, the majority of problems with foot ulcer recurrence in diabetes can be resolved. It is therefore time to act and to set a new target in diabetic foot care. This target is to reduce foot ulcer incidence with at least 75%. Copyright © 2016 John Wiley & Sons, Ltd.

Keywords foot ulcer; prevention; recurrence; adherence; costs; classification

Bus, SA., and van Netten, JJ. (2016) A Shift in Priority in Diabetic Foot Care and Research: 75% of Foot Ulcers are Preventable. *Diab Metab Res Rev*, 32: 195–200.

- The strongest predictor of diabetic foot ulceration is a previous foot ulcer
- In Europe, for every euro spent on ulcer prevention, ten are spent on ulcer healing. Similarly, in the research market, for every randomized clinical trial conducted on prevention, ten are conducted on healing.

Prevention of Foot Ulcers

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Strategies for DFU Prevention

Physician

- Patient education
- Routine foot care
- Foot surgery

Patient Self-Management

- Daily self-examination
- Consistent use of diabetic footwear
- ***Temperature monitoring***

Multidisciplinary Approach *and* Evidence Based Algorithms

*Previous studies have demonstrated a reduction of major amputations by **up to 80%** simply in centers that function as a multidisciplinary group.*

- Centers of Excellence
- Mid-level providers
- Surveillance
- Strong focus on prevention
- Appropriate and timely consultations
- Expedited management of complicated patients



The cost of curative care is **5-30 times greater** than cost of preventive care

Hicks, CW et al. Trends and determinants of costs associated with the inpatient care of diabetic foot ulcers. *J Vasc Surg* 2014. Volume 60 (5) 1247–1254



POLL QUESTION

Should Diabetes be Managed with Telemedicine?

Consensus paper based on international guidelines and EBM research.

38 recommendations for key issues in telemedicine management of DM

- Suitable scenarios
- Suitable populations
- Data collection and assessment
- Education and behavior management
- Diet
- Exercise rehabilitation
- Medication management



Diabetes is very suitable for telemedicine management

Should Diabetes be Managed with Telemedicine?

Strong recommendations:

- Teams should include physicians in relevant specialties, diabetes education nurses, dietitians, and tele-managers
- Conduct comprehensive assessment, monitor, and promote early screening for diabetes and its complications
- Type 2 diabetes mellitus (T2DM)
- Part of the physical examination can be conducted via video, such as checking skin lesions and foot ulcers or skin abnormalities at the insulin injection site
- **Patients with mental illness, cognitive impairment, and acute diabetes complications should not receive tele-management**

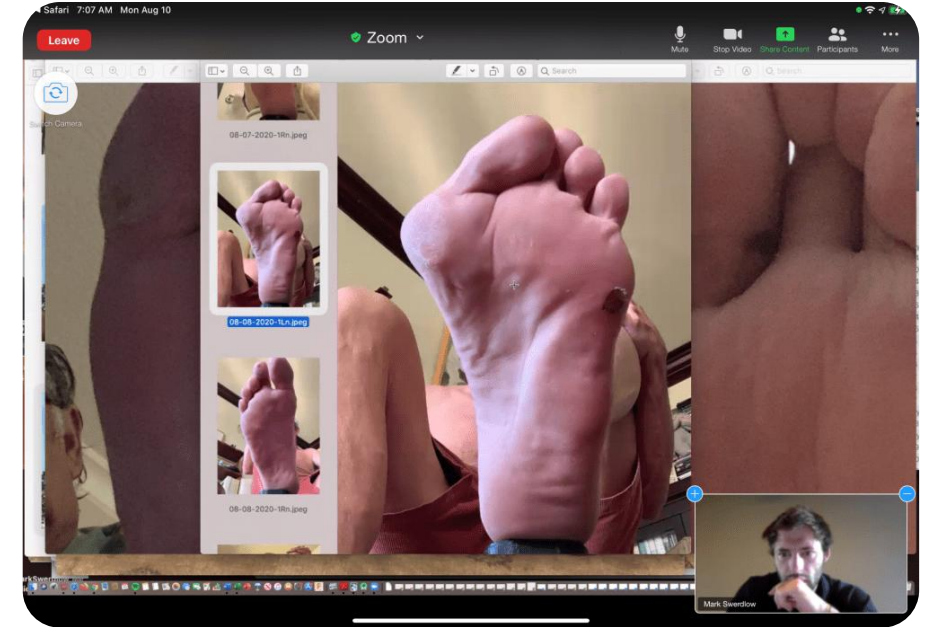
DFU Healing and Telemedicine

374 Patients with DFU

- 193 received telemedicine - teleconsultation and traditional care at an outpatient clinic
- 181 patients received only outpatient clinic visits

After One Year Follow Up

- Statistically similar rates of amputations
- Telemedicine patients significantly higher mortality rate without clear underlying reasons
- 72% of the telemedicine group showing complete ulcer healing while 73% of the controls showed complete ulcer healing



Rasmussen BS, Froekjaer J, Bjerregaard MR et al. A randomized controlled trial comparing telemedical and standard outpatient monitoring of diabetic foot ulcers. Diabetes Care 2015; 38(9):1723–1729

Confidential. Do not copy. Do not distribute.

DFU Healing and Telemedicine

Purpose: Explore health care professionals' experience in the initial phase of introducing telemedicine technology in caring for people with diabetic foot ulcers.

Focus Groups

- 29 Nurses
- 1 Nurse assistant
- 2 Podiatrists
- 2 Physicians

Table 1 Topics in the interview guide

- Participants' experiences in using telemedicine, and how it was organized where they work
- Participants' experiences in using telemedicine as a new tool in documentation and communication
- Participants' experiences in communication and collaboration between outpatient clinic (physicians, nurses and foot therapists) and nurses in home care through tele-communication, and among professions
- Changes in their competence in caring for people with diabetes foot ulcers during the intervention
- Changes in their job satisfaction while using telemedicine

Koltveit et al. BMC Health Services Research (2016) 16:134
DOI 10.1186/s12913-016-1377-7

BMC Health Services Research

RESEARCH ARTICLE

Open Access

Telemedicine in diabetes foot care delivery: health care professionals' experience



Beate-Christin Hope Koltveit^{1*}, Eva Gjengedal^{2,3}, Marit Graue¹, Marjolein M. Iversen^{1,4}, Sally Thorne⁵ and Marit Kirkevold^{1,6}

DFU Healing and Telemedicine

Participants experienced meaningful changes benefitting their practice in three ways:

- **Increased wound assessment knowledge and skills**
 - Using images as well as electronic text in the web-based ulcer record facilitated increased dialogue and more reflection around wound treatment between colleagues
- **Improved documentation quality**
 - Web based ulcer record required that health care professionals follow the same standards in reporting their findings
- **Streamlined communication between primary care and specialist care**
 - It was easier for them to reach the right person on the other end when they wanted to discuss or pass along messages about a case

Koltveit et al. *BMC Health Services Research* (2016) 16:134
DOI 10.1186/s12913-016-1377-7

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The Role of Technology and Medicine

Three biggest problems facing healthcare today:

- 1 Cost**
- 2 Access**
- 3 Staffing**

**Technology should
add efficiency**

The most influential factor in healthcare today:

Patient–Provider Trust

**Technology should
build upon trust**

Where Technology is Helping

Faster & More Accurate Access to Patient Records

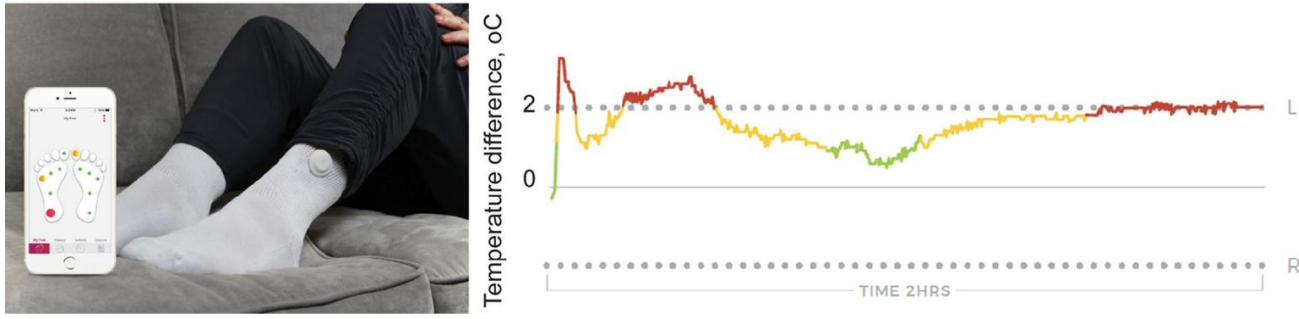
- EHRs make patient health information **instantly accessible** to providers and patients by supporting **automated workflows** between people and technologies.
 - **Patient Portals**
 - **Scheduling**
 - **Challenge: Portability**

Improved Access to Care

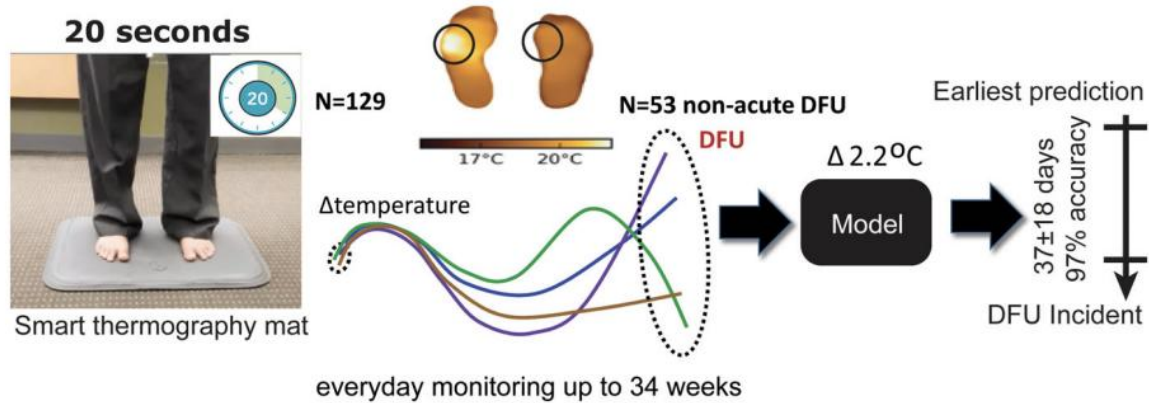
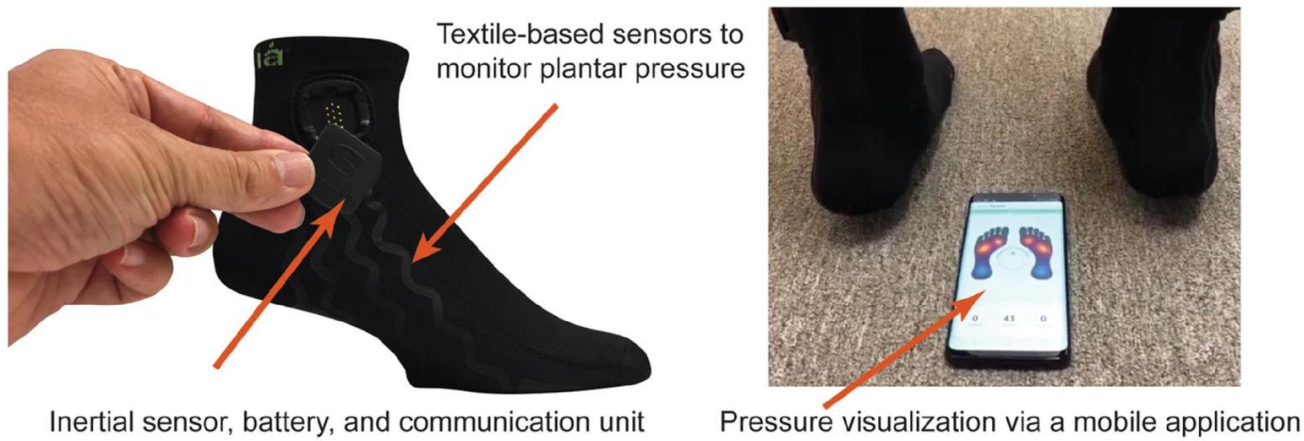
- Healthcare access is one of the **main barriers to quality care**. Cost, distance, and physical limitations often **prevent patients from receiving the care that they need**, leading to **delayed treatment**. Disadvantaged populations are **particularly affected**. Telehealth, for example, has proven to **reduce emergency room visits** and **lower costs** for patients and providers.

Better Diagnostics

- Technology has **improved diagnostics** in every way—from accuracy, to speed, to accessibility. Diagnostic technology plays a **key role** in addressing one of the biggest issues in healthcare: **chronic illness**.



Sensoria sock+Sensoria App



Najafi, B et al. Leveraging smart technologies to improve the management of diabetic foot ulcers and extend ulcer-free days in remission. *Diab Metab Res Rev*, 2020

Foot Temperature Monitoring

Thermometry for the diabetic foot first emerged in the 1970s.¹⁻⁵



KEY WORDS: Extremities; inflammation; stress, mechanical; thermography

Thermography: An Aid in the Management of Insensitive Feet and Stumps

Harry T. Bergtholdt, M.S., L.P.T., Paul W. Brand, C.B.E.

• Infrared thermography contributes to the care of insensitive limbs. The inflammatory response of near damaged or damaged tissue presents areas of increased heat on the surface which can be detected and followed. Thermography was found to be a valuable aid to the established management methods used for insensitivity problems including management of healing and freshly healed ulcerations, management of neuropathic bone and joint problems and fitting of prosthetic devices and custom shoes. The most important contribution thermography offered was the detection of irritated tissue prior to frank breakdown often in time to prevent permanent injury if quick and effective management followed.

Detection and management of problems associated with stress to insensitive tissue are difficult at best. Early detection is necessary for measures to be effective in preventing serious complications such as ulcer-

heat a useful guide to the response of the soft tissue to excessive repetitive stresses from working and walking. Harris and Brand,¹ in 1966, recognized the importance of an area of warmth as the earliest warning of the onset of bone disintegration when preventive measures would still be effective. Sandrow and his associates³ found thermography to be a valuable diagnostic tool in the early detection of the diabetic neuropathic arthropathy.

Thermography is a technique that measures the surface temperatures of an area of the body, and forms a temperature picture called a thermogram. Employing a gray scale, the temperatures are shown from cool (black) to warm (white). Thus, an area of inflammation will be noted on the thermogram as a white area (or "hot spot"). The temperature dif-

Bergtholdt. Rehab Serv Adm 1977.
Bergtholdt HT. Phys Ther. 1979.

Bergtholdt et al. Arch Phys Med Rehab. 1975.

Beach RB, et al. Phys Ther. 1979.

Manley et al. Arch Phys Med Rehab.

1980

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Foot Temperature Monitoring



Three RCTs have since examined the impact of identifying and off-loading patients with new plantar “hotspots” (temperature-guided avoidance therapy, TGAT) vs. standard prevention therapy on recurrence of ulceration in high-risk individuals.

The mean relative DFU reduction among the three RCTs was 72%.

Study	N	Follow-up period	Recurrence, Standard of Care	Recurrence, TGAT	Relative Reduction
Lavery 2004	85	6 months	15.9%	2.4%	85%
Lavery 2007	173	15 months	29.3%	8.5%	71%
Armstrong 2007	225	18 months	12.2%	4.7%	61%
				Mean	72 %

Foot Temperature Monitoring

Thermometry is a clinically established DFU prevention technique.

American College of Foot and Ankle Surgeons 2006¹

“Diabetic patients at risk for foot lesions must be educated about risk factors and the importance of foot care, including the need for self-inspection and surveillance, monitoring foot temperatures...”

International Working Group on the Diabetic Foot (IWGDF) 2016²

“Instruct a high-risk patient (IWGDF risk classification 2 or 3) to monitor foot skin temperatures at home to prevent a first or recurrent plantar foot ulcer. This aims at early recognition of inflammation followed by action taken by the patient and care provider to resolve the cause of inflammation.”

Wound Health Society 2016³

“Home monitoring of foot temperatures with an infrared thermometer reduces re-ulceration (Level I)... By daily assessment of temperature changes, patients could identify early warning signs of tissue inflammation and reduce their activity to avert the development of an ulceration.”

Agency for Healthcare Research and Quality 2017⁴

“Home monitoring of foot skin temperature, therapeutic footwear, and integrated foot care are effective for preventing foot ulcers”

Frykberg et al. J Foot Ankle Surg. 2006;45(5 Suppl):S1-66.

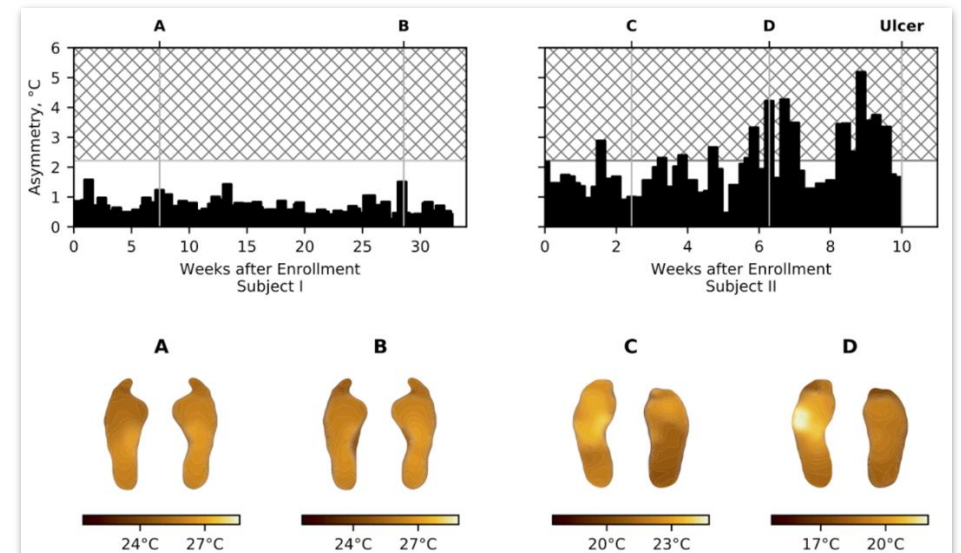
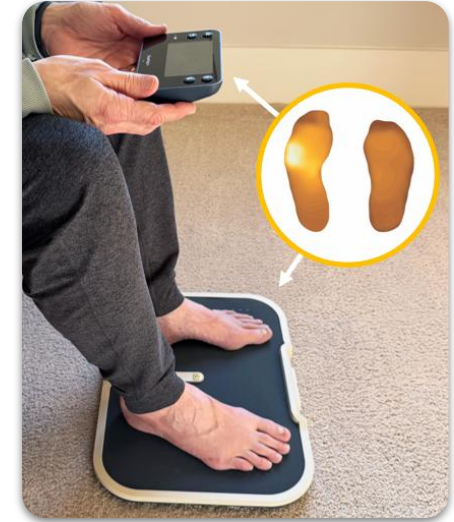
Bus et al. Diabetes Metab Res Rev 2016 Jan;32 Suppl 1:16-24.

Lavery et al. Wound Rep Reg. 2016;24 112–126.

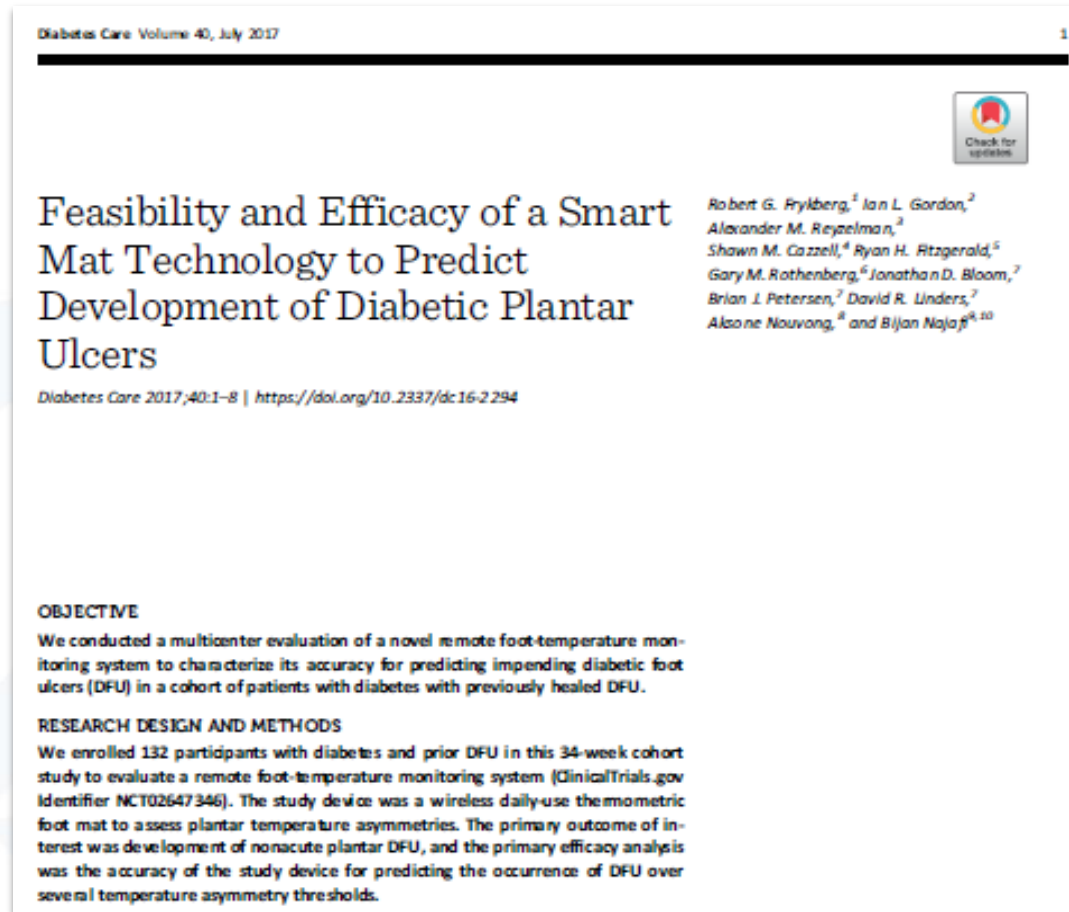
Dy SM, et al. AHRQ Publication No. 17-EHC005-EF.

Foot Temperature Monitoring

- In-home telemedicine system designed to remotely monitor and analyze temperature asymmetry
- Daily use wireless mat with 2000 temperature sensors under a water resistant mat
- Step on the mat for 20 seconds
- The device records a temperature scan (thermogram) of the feet
- Data are saved, processed, and analyzed for asymmetry
- Care support is provided to patients
- Protocols designed for intervention
- Clinical escalations, as warranted



RTM Diabetes Care Study



Frykberg, RG et al, Feasibility and Efficacy of a Smart Mat Technology to Predict Development of Diabetic Plantar Ulcers. *Diabetes Care* Apr 2017

- Multi-center (three VAMCs) trial in 129 participants with history of DFU
- Participants followed for 34 weeks each with standard preventative foot care and Podimetrics SmartMat
- Non-interventional study
- 86% of patients met target adherence (>3 days/week), and 88% reported SmartMat was “easy” to use.

The SmartMat correctly identified **97% of observed DFU** at an average **lead time of 37 days**

Evidence Based Outcomes with RTM

BMJ Open
Diabetes
Research
& Care

Unilateral remote temperature monitoring to predict future ulceration for the diabetic foot in remission

Lawrence A Lavery,¹ Brian J Petersen,² David R Linders,³ Jonathan D Bloom,² Gary M Rothenberg,³ David G Armstrong⁴

Detection & Implication

- **91%** of foot ulcers detected at approximately **41 day** lead time
- **40%** current SmartMat users are single foot scanners

Lavery et al. BMJ Open 2019

ORIGINAL RESEARCH

Remote Temperature Monitoring of the Diabetic Foot: From Research to Practice



PDF DOWNLOAD

Fed Pract. 2020 March;37(3):114-124

Author(s): Gary M. Rothenberg, DPM, CDE, CWS; Jeffrey Page, DPM; Rodney Stuck, DPM; Charles Spencer, DPT; Lonnie Kaplan, DPM; Ian Gordon, MD

Intervention & Clinical Action

- **68%** of inflammation detected resolved via off-loading alone
- **76%** of patients reported clinically meaningful preventive care when alerts prompted office visits

Rothenberg et al. Fed Practitioner 2020

BMJ Open
Diabetes
Research
& Care

Lower resource utilization for patients with healed diabetic foot ulcers during participation in a prevention program with foot temperature monitoring

Adam L Isaac,^{1,2} Timothy D Swartz,¹ Mark L Miller,¹ Daniel J Short,¹ Eleanor A Wilson,¹ Jamie L Chaffo,¹ Eric S Watson,³ Haihong Hu,³ Brian J Petersen,⁴ Jonathan D Bloom,⁴ Nicole J Neff,⁴ David R Linders,⁴ Simon J Salgado,⁴ Jessica L Locke,¹ Michael A Horberg^{1,3}

Impact on Outcomes

- **71%** reduction in diabetes related amputations
- **52%** reduction in all-cause inpatient admissions
- **40%** reduction in ED visits

Isaac et al. BMJ Open 2020

SmartMat+ Remote Temperature Monitoring Program

Keeping the most vulnerable patients with diabetes out of the hospital with their limbs intact

EVIDENCE-BASED TEMPERATURE MONITORING APPROACH WITH CLINICAL INTERVENTIONS

SMARTMAT+ MONITORING



- Once-daily, at-home monitoring
- 20 seconds to scan
- Cellularly connected – no need for app, Bluetooth or WiFi
- Visual interface for instant feedback
- Monitors for weight fluctuation

- Detects inflammation via remote temperature monitoring
- Monitors balance & stability for potential fall-risk

Early Detection

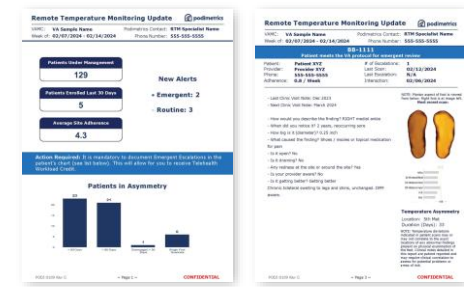
PATIENT ENGAGEMENT



- Multi-modal engagement and support (e.g., telephonic, text)
- Instructs offloading when inflammation is detected
- Able to assess additional health risks

Effective at-home offloading

PROVIDER SUPPORT



- Escalations and alerts to provider
- Identifies need for intervention and follow up physician visit
- Line of sight into patients in between visits

Targeted low-cost intervention

Supporting and Collaborating with Health Plan Care & Disease Management + Quality Oversight

Regional Health Plan: 17-month Retrospective

- n = 300 participating members (activated) were analyzed for the program
 - 1,654 in the control group (eligible, non-enrolled)

Results Highlights

- Members with DFU history in program showed a **~16% Total Cost of Care savings rate**
 - Savings are driven by reductions in IP visits, repeat DFUs, and amputations
- Members with DFU history in program showed:
 - **69.7% amputation rate reduction**
 - **29.5% IP (inpatient) reduction**
 - **6.9% repeat DFU reduction**

Regional Health Plan: 17-month Retrospective

Social History Demographics (Patient Reported)*

% Reporting Social History	60.86%
% Living Alone	36.1%
% Has Caregiver	71.99%
% Working	1.89%
% Smoking	27.39%
% Using Mobility Aid	71.78%
% Wears Therapeutic Shoes	13.69%
% Patients Reporting Fall During Past Year	56.64%

* Patient reported medical and social history is not available for all patients (see % Reporting Medical / Social History). Medical and social history demographics are reported for patients with available data.

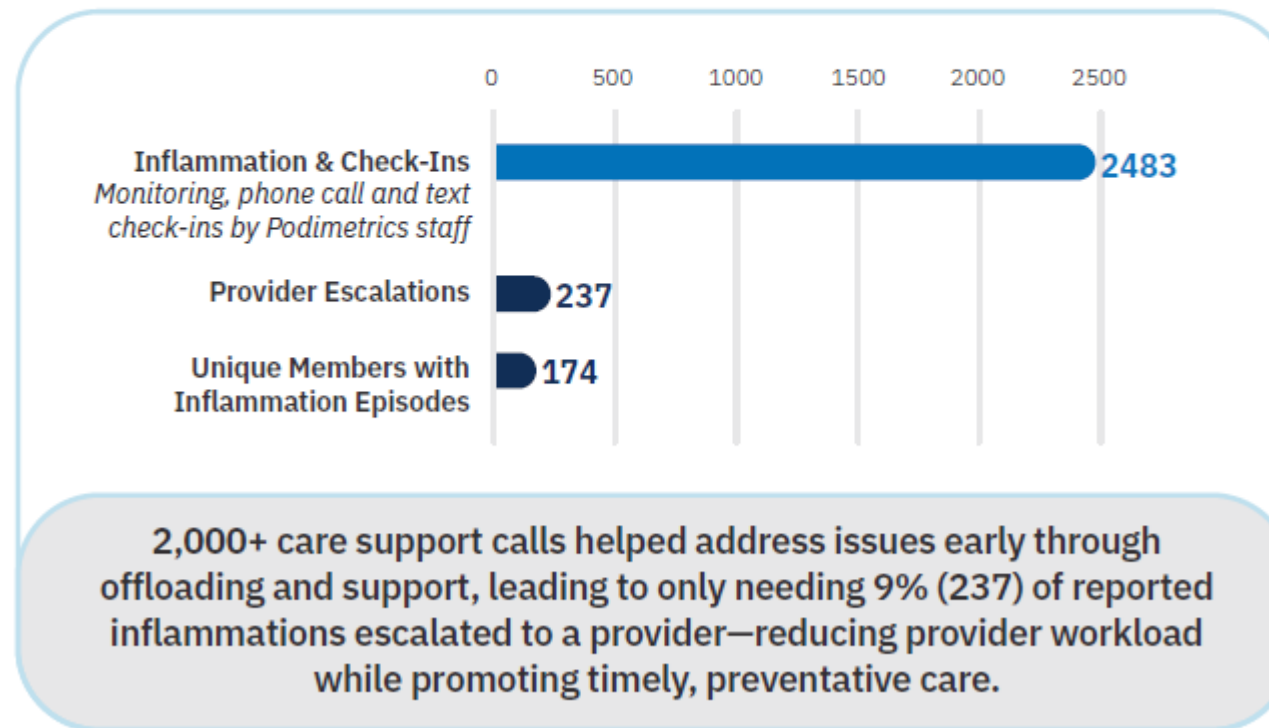
% Reporting Medical History	61.99%
% Dialysis	6.52%
% Neuropathy	78.82%
% Vascular Complications	82.08%

Regional Health Plan: 17-month Retrospective

Clinical Review

Provider advisories, escalations, and inflammation trends

Escalations Related to Foot Health and Wound Detection



Regional Health Plan: 17-month Retrospective

Patients and Providers consistently report high satisfaction with the program

Patients

Health plan satisfaction due to the program **8.9/10**

Peace of mind knowing it can detect early signs of inflammation **4.8/5**

SmartMat ease of use **4.9/5**



"Helped me get in a habit of checking my BP and taking my meds"

Providers

Overall program satisfaction **9.5/10**

Satisfaction with the service **9.8/10**
(education, onboarding, and clinical support)

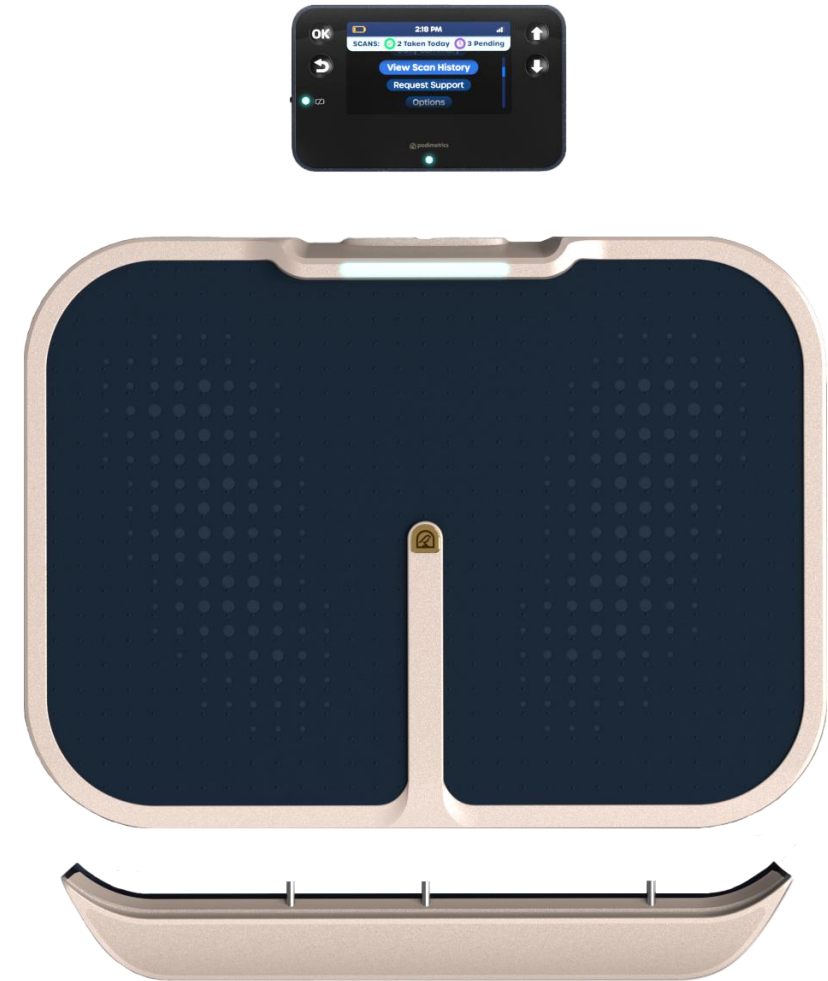
The program has an impact on care **91%**

Recommends to other providers **100%**

"We have seen it work on preventing further wounds on the feet. It truly saves money from treating wounds."



SmartMat vs SmartMat+



Falls and the Complex Patient with Diabetes

General
Population



Complex Patient with
DFU Risk

Falls Have a Significant Impact on Patient Health¹

- **1 in 3 adults** aged 65+ experience falls each year
- **Half** of these patients fall multiple times per year
- **3M** elderly falls, each costing **\$19k - \$37k per fall^{2,3}**



Patients at High Risk for Foot Ulcers are also at High Risk of Falling...

- **Diabetes, age, gait impairment** are all risk indicators for greater fall risk⁴
- **75% of Podimetrics enrolled patients** have a fall history or high concern of future fall⁶

...with more significant cost & health implications

- Higher rate of injury, fracture, and hospitalization⁷
- Diabetic neuropathy patients are **15x more likely to report injury** due to instability⁵
- Home Health or LTC needs for recovery
- Loss of independence and increased risk of depression



POLL QUESTION

SmartMat+ Fall Risk Pilot: 6 month progress

Regional Health Plan + Podimetrics | Jan – June 2026 | Month 6 of Pilot

182 patients currently enrolled

Key Actions/Plan Follow Up

- PT referrals for 69 patients with balance problems
- Assistive device audit for 71 patients
- Medication review for 36 patients reporting dizziness
- High risk follow-up: 57 patients report a recent fall

ALL MODIFIABLE RISK FACTORS — CUMULATIVE

Home hazards present		38% 69
Balance problems		38% 69
Use assistive device		39% 71
Fall in last 12 months		31% 57
Provider recommendations		28% 51
Spoken with provider re: fall		23% 42
Medication / dizziness		20% 36

PATIENT SATISFACTION

4.9 out of 5 – Overall Device Satisfaction

4.7 out of 5 – Ease of Use

4.8 out of 5 – Fall Risk Visibility

Conclusion

- The goal of all prevention is to avoid morbidity and mortality
- Prevention strategies to minimize foot ulcer recurrence are a shared burden by the provider and the patient
- Telemedicine and technology allow providers to identify emerging, potentially serious health concerns – augment prevention strategies and triage
- Surprisingly, there is a strong human component to telemedicine – relationships are built
- Embrace innovations and technology early



**Thank you for your
participation!**

Questions?
Thoughts?

Visit our VBCExhibitHall Virtual booth

Click picture to Visit!



THANK YOU!



<https://podimetrics.com/>

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