Contents lists available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.journals.elsevier.com/diabetes-research-and-clinical-practice

Artificial intelligence for automated detection of diabetic foot ulcers: A real-world proof-of-concept clinical evaluation

Bill Cassidy[a,*], Moi Hoon Yap[a], Joseph M. Pappachan[b], Naseer Ahmad[c], Samantha Haycocks[d], Claire O'Shea[e], Cornelius J. Fernandez[f], Elias Chacko[g], Koshy Jacob[h], Neil D. Reeves[i]

[a] Department of Computing Mathematics, Manchester Metropolitan University, John Dalton Building, Manchester M1 5GD, UK
[b] Lancashire Teaching Hospitals NHS Foundation Trust, Preston PR2 9HT, UK
[c] Manchester University NHS Foundation Trust, Manchester M13 9WL, UK
[d] Salford Royal NHS Foundation Trust, Stott Lane, Salford M6 8HD, UK
[e] Te Whatu Ora Health New Zealand Waikato, Pembroke Street, Hamilton 3240, New Zealand
[f] Department of Endocrinology and Metabolism, Pilgrim Hospital, United Lincolnshire Hospitals NHS Trust, Boston LN2 5QY, UK
[g] Jersey General Hospital, The Parade, St Helier, JE1 3QS Jersey, UK
[h] Eastbourne District General Hospital, Kings Drive, Eastbourne BN21 2UD, UK
[i] Faculty of Science & Engineering, Manchester Metropolitan University, John Dalton Building, Manchester M1 5GD, UK

A B S T R A C T

Objective: Conduct a multicenter proof-of-concept clinical evaluation to assess the accuracy of an artificial intelligence system on a smartphone for automated detection of diabetic foot ulcers.

Methods: The evaluation was undertaken with patients with diabetes ($n = 81$) from September 2020 to January 2021. A total of 203 foot photographs were collected using a smartphone, analysed using the artificial intelligence system, and compared against expert clinician judgement, with 162 images showing at least one ulcer, and 41 showing no ulcer. Sensitivity and specificity of the system against clinician decisions was determined and inter- and intra-rater reliability analysed.

Results: Predictions/decisions made by the system showed excellent sensitivity (0.9157) and high specificity (0.8857). Merging of intersecting predictions improved specificity to 0.9243. High levels of inter- and intra-rater reliability for clinician agreement on the ability of the artificial intelligence system to detect diabetic foot ulcers was also demonstrated ($K\alpha > 0.8000$ for all studies, between and within raters).

Conclusions: We demonstrate highly accurate automated diabetic foot ulcer detection using an artificial intelligence system with a low-end smartphone. This is the first key stage in the creation of a fully automated diabetic foot ulcer detection and monitoring system, with these findings underpinning medical device development.

1. Introduction

Diabetic foot ulcers (DFUs) and associated amputations are a global health and economic burden. In the United Kingdom, they account for 10% of the diabetes health services budget [14]. A reduction of DFU cases by one-third would result in a gross annual saving of more than £250 GBP million in the UK [16]. In the United States, the cost related to DFU is estimated to be approximately $9–13 USD billion in addition to the cost associated with diabetes [15]. Patients with diabetes have a lifetime risk of up to 34% of developing a DFU, with more than half of all cases leading to infection [4]. DFU is considered to be a clinical marker for increased risk of amputation and mortality [19,11].

Smartphone healthcare apps and associated research has seen notable growth in recent years, with increased engagement with self-monitoring health apps [3,23]. Artificial intelligence (AI) has been used in recent studies for real-time screening of diabetic retinopathy [3] (*accuracy* = 94.7%), diabetes prediction using lifestyle data [28] (*accuracy* = 82.1%), and screening for pre-diabetes in children and adolescents [29] (*accuracy* = 90.13%). AI applications are also being developed for other clinical areas such as endometriosis screening [30] and screening for genetic syndromes in children [31]. These studies showed promising results, indicating the potential importance of AI in clinical settings.

There have also been numerous advances in the use of AI for automated and semi-automated DFU screening, detection, and monitoring. Brown et al. [6] developed the MyFootCare smartphone app, which

* Corresponding author.
E-mail addresses: bill.cassidy@stu.mmu.ac.uk (B. Cassidy), m.yap@mmu.ac.uk (M. Hoon Yap), pappachan.joseph@lthtr.nhs.uk (J.M. Pappachan), naseer.ahmad@mft.nhs.uk (N. Ahmad), sam.haycocks@hotmail.co.uk (S. Haycocks), claire.o'shea@waikatodhb.health.nz (C. O'Shea), cornelius.fernandez@ulh.nhs.uk (C.J. Fernandez), e.chacko@health.gov.je (E. Chacko), k.jacob1@nhs.net (K. Jacob), n.reeves@mmu.ac.uk (N.D. Reeves).

https://doi.org/10.1016/j.diabres.2023.110951
Received 18 April 2023; Received in revised form 2 October 2023; Accepted 11 October 2023
Available online 15 October 2023
0168-8227/© 2023 The Author(s). Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).