TPM Vol. 32, No. S2, 2025
ISSN: 1972-6325
https://www.tpmap.org/

DEVELOPMENT AND EVALUATION OF A NOVEL MOBILE-BASED SMARTPHONE APPLICATION FOR DIABETIC FOOT ULCER CARE USING REGULAR WOUND PHOTOGRAPHS, VIDEOS, AND CHAT-BASED COMMUNICATION TO PREVENT COMPLICATIONS: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background:
Diabetic foot ulcers (DFUs) are a leading cause of lower-limb amputation, disability, and mortality in patients with diabetes. Poor follow-up, inadequate monitoring, and delayed intervention are major contributors to complications.

Objective: To evaluate the efficacy of a novel mobile-based smartphone application for DFU care compared with conventional follow-up in improving ulcer healing, reducing complications, and enhancing adherence.

Methods: A single-center, prospective, randomized controlled trial was conducted involving 60 diabetic patients with Wagner grade 1–4 foot ulcers. Participants were randomized into two groups: the intervention group (n=30) received the mobile application for daily wound image/video uploads, automated reminders, and direct chat with clinicians; the control group (n=30) received standard outpatient care. Outcomes measured over 24 weeks included ulcer healing rate, healing time, medication adherence, and glycemic control (HbA1c levels)

Results: Complete ulcer healing occurred in 50% of app users compared to 16.7% in the control group (p=0.0346). Mean healing time was significantly shorter in the intervention group (11.85 ± 4.57 weeks) compared to controls (13.17 ± 4.79 weeks, p=0.0001). Medication adherence was significantly higher in the intervention group (89.86% ± 5.67) compared to controls (66.6% ± 10.25, p<0.0001). No significant difference was observed in final HbA1c, though trends favored the intervention group.

Conclusion: The novel mobile application significantly improved ulcer healing rates, reduced healing time, and enhanced medication adherence. Digital health solutions hold promise as adjunctive tools in DFU management, particularly in resource-limited settings.

Keywords: diabetic foot ulcer, mobile health, wound care, smartphone application, randomized controlled trial

INTRODUCTION

Diabetic foot ulcers (DFUs) represent a major complication of diabetes mellitus, affecting up to 25% of patients during their lifetime. DFUs are associated with high morbidity, increased risk of amputation, and substantial healthcare costs. Effective management requires regular monitoring, patient engagement, and timely intervention — aspects often compromised in low-resource settings.

Recent advances in mobile health (mHealth) provide opportunities for remote patient monitoring and continuous communication between patients and healthcare providers. However, limited evidence exists on the role of mHealth in DFU-specific management. This study evaluates a novel smartphone-based application designed to enhance DFU care by enabling wound monitoring through images/videos, providing educational content, and facilitating real-time clinician communication.

MATERIALS AND METHODS:

RESEARCH DESIGN:

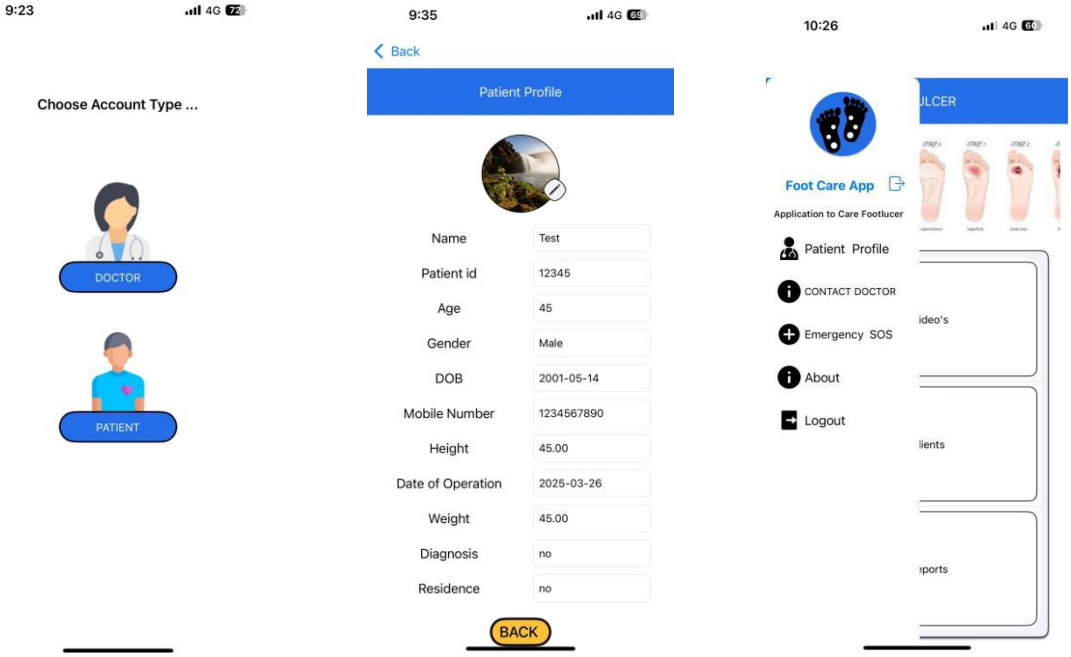
PICO :

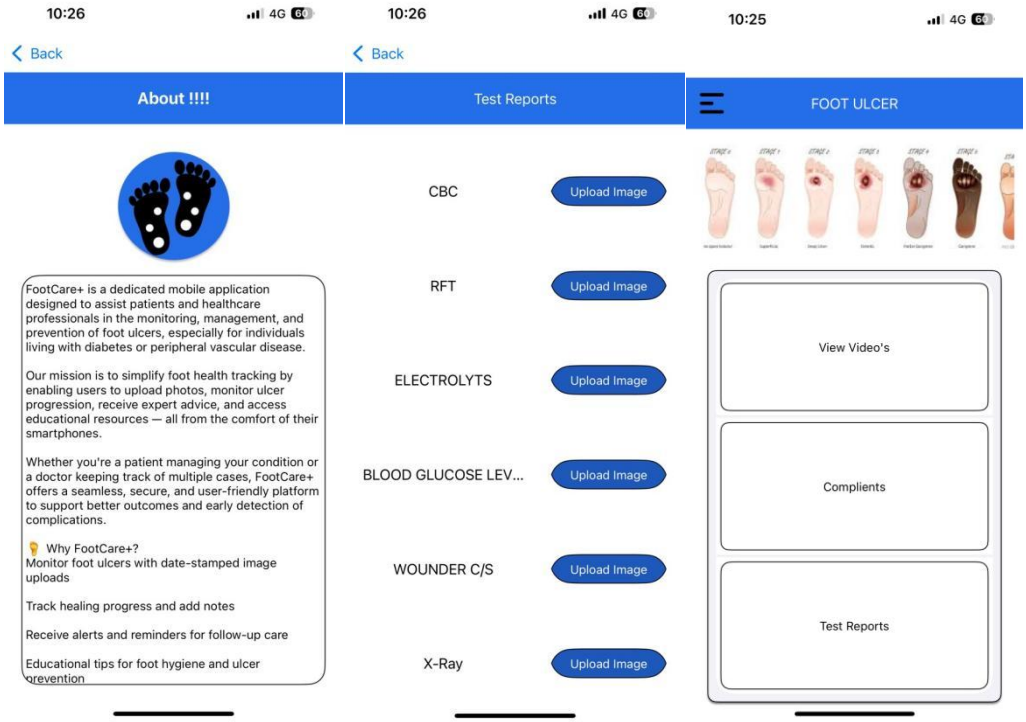
- P (Population): Diabetic patients with foot ulcers.
- I (Intervention): Mobile application for wound monitoring (photographs, videos, chat-based communication).
- C (Comparison): Standard care (routine follow-up without app use and with regular OPD follow up).
- O (Outcomes):
  - Improved ulcer healing rates.
  - Reduced complications (infections, amputations).
  - Enhanced patient adherence and communication.

Study design: Prospective observational study

Study tool:

- Mobile application with tabs to enter photographs/ videos of diabetic foot ulcer and their daily monitoring
- Methods of data collection: Data will be collected for every patient with diabetic foot ulcers:
- Patient will upload photographs/ videos of the ulcers and the doctor will assess the wound status on as daily basis.
- App will contain entire history of the patient including lab investigations, wound photographs, intra operative pictures, proper dressing techniques etc





DATA COLLECTION:

- Basic patient data (Name, age, gender etc)
- Detailed history of the patient and examination of the ulcer at the time of presentation to the hospital.
- Complete history of lab investigations since day of admission to hospital
- Intra operative procedure notes and intra operative wound pictures
- Daily uploading of the wound pictures or videos by the patient which will be monitored by the treating doctor.
- Daily monitoring of CBG at least for a period of 1 week after discharge from hospital.

STATISTICAL ANALYSIS:

- **Inclusion criteria:**
  - Patients who are willing to undergo the study.
  - Patients with diabetic foot ulcers
  - Patients who have basic knowledge of using smartphone
- **Exclusion criteria:**
  - Patients who are not willing to undergo the study.
  - Patients with ulcers with etiology other than diabetes mellitus e.g. venous ulcers, traumatic ulcers, malignant ulcers.
  - Patients with no smartphone for using the app.
- **Sample size:**
  - 30 patients with diabetic foot ulcer using the mobile application; 30 patients not using the mobile application
- **Sampling technique:** Random sampling Method

Randomization and Intervention:

Patients were randomly assigned into:

- **Intervention group:** Received the mobile application with features for daily wound image/video uploads, chat-based communication with clinicians, automated medication reminders, and educational modules.
- **Control group:** Received standard outpatient follow-up with in-person visits at scheduled intervals.

Results:

Primary outcomes:

- Rate of complete ulcer healing within 24 weeks
- Mean time to healing

Secondary outcomes:

- Medication adherence (self-reported and app-logged)

- Glycemic control (HbA1c and capillary blood glucose monitoring)

Statistical Analysis

Data were analyzed using SPSS v26. Continuous variables were expressed as mean ± SD and compared using t-tests. Categorical variables were compared using chi-square or Fisher's exact test. $p<0.05$ was considered statistically significant.

Results

Baseline Characteristics

Both groups were comparable in age, gender, BMI, ulcer grade, and duration of diabetes ($p>0.05$).

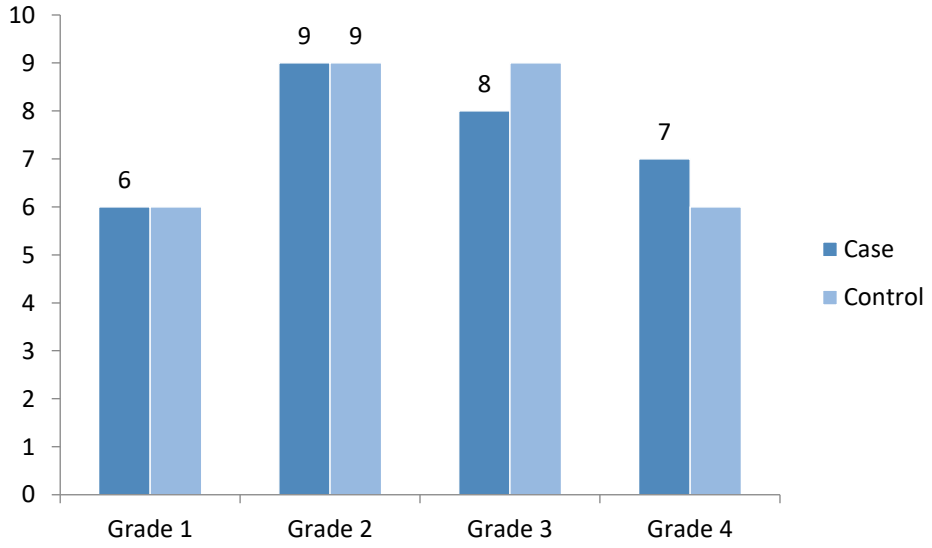
Primary Outcomes

Ulcer healing rate: 50% (15/30) in intervention vs 16.7% (5/30) in control ($p=0.0346$)

Comparison of baseline ulcer grade:

Among the case group, 6 individuals (20%) presented with Grade 1 ulcers, 9 (30%) with Grade 2, 8 (26.67%) with Grade 3, and 7 (23.33%) with Grade 4 ulcers. In the control group, 6 patients (20%) had Grade 1 ulcers, 9 (30%) had Grade 2, 9 (30%) had Grade 3, and 6 (20%) presented with Grade 4 ulcers. The difference in baseline ulcer severity between the two groups was not statistically significant (P = 0.9872), indicating that both groups were similar in terms of initial ulcer grade distribution at the time of enrollment.

Ulcer Grade	Case	Control	P Value
Grade 1	6(20%)	6(20%)	0.9872
Grade 2	9(30%)	9(30%)	
Grade 3	8(26.67%)	9(30%)	
Grade 4	7(23.33%)	6(20%)	



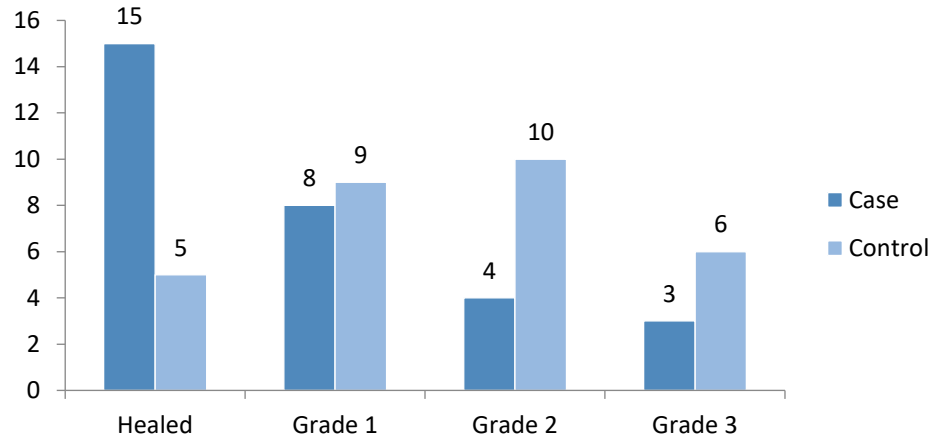
Comparison of baseline ulcer grade

Comparison of final ulcer grade:

Among the cases, 15 patients (50%) had completely healed ulcers, whereas only 5 patients (16.67%) in the control group achieved complete healing. Ulcers that remained at Grade 1 were observed in 8 patients (26.67%) in the case group and 9 patients (30%) in the control group. Grade 2 ulcers were seen in 4 cases (13.33%) and 10 controls (33.33%), while Grade 3 ulcers persisted in 3 cases (10%) and 6 controls (20%). The difference in final ulcer outcomes between the two groups was statistically significant (P = 0.0346), suggesting that the mobile application had a positive impact on ulcer healing and overall wound care management.

Ulcer Grade	Case	Control	P Value
Healed	15(50%)	5(16.67%)	0.0346*
Grade 1	8(26.67%)	9(30%)	
Grade 2	4(13.33%)	10(33.33%)	
Grade 3	3(10%)	6(20%)	

Table 8: Comparison of final ulcer grade



Comparison of final ulcer grade

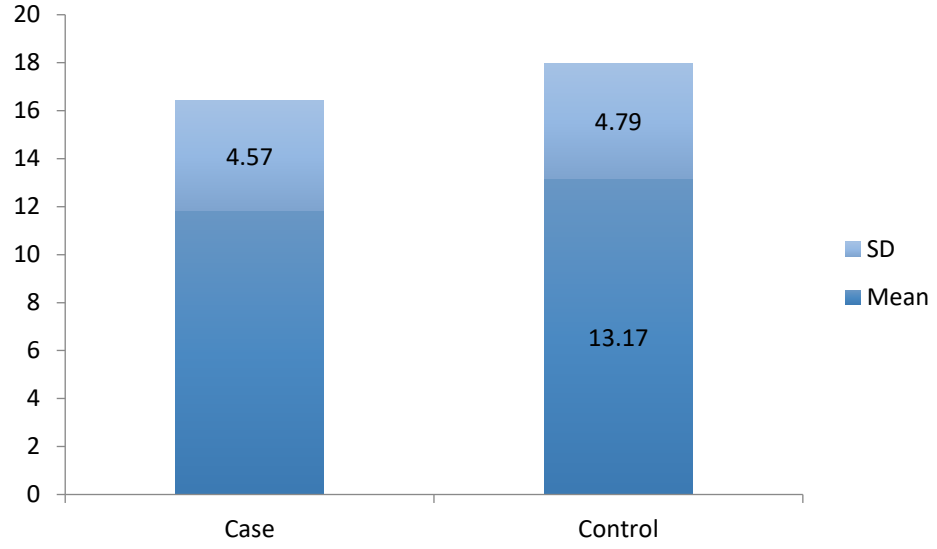
Healing time: 11.85 ± 4.57 weeks in intervention vs 13.17 ± 4.79 weeks in control (p=0.0001)

Comparison of healing time:

The average healing time was significantly shorter in the group using the mobile application compared to the control group. Patients in the case group experienced a mean healing duration of 11.85 ± 4.57 weeks, whereas the control group had a longer average healing time of 13.17 ± 4.79 weeks. The difference between the two groups was found to be statistically significant (P = 0.0001), indicating that the mobile app contributed to faster wound healing in diabetic foot ulcer patients.

Healing Time (weeks)	Case	Control	P Value
	11.85 ± 4.57	13.17 ± 4.79	0.0001*

Comparison of healing time



Comparison of healing time

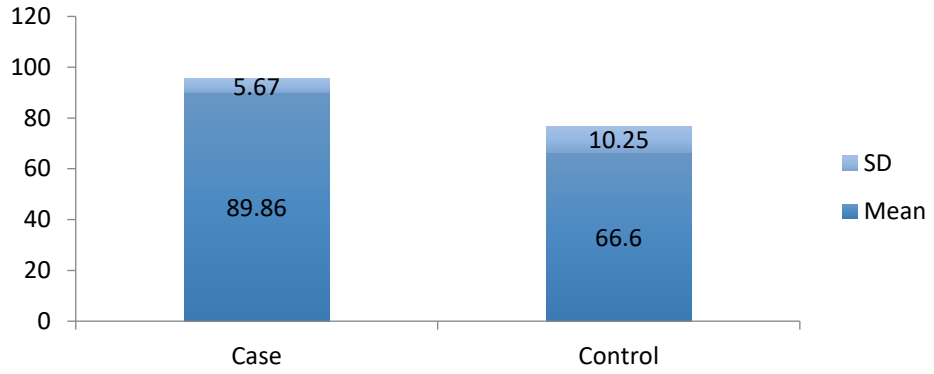
Secondary Outcomes

Medication adherence: 89.86% ± 5.67 in intervention vs 66.6% ± 10.25 in control (p<0.0001)

Medication adherence was significantly higher among patients who used the mobile application compared to those who did not. The case group demonstrated a mean adherence rate of 89.86% ± 5.67, whereas the control group showed a much lower adherence of 66.6% ± 10.25. This difference was highly statistically significant (P < 0.0001), highlighting the positive impact of the app in improving patient compliance with prescribed medications.

Medication Adherence (%)	Case	Control	P Value
	89.86 ± 5.67	66.6 ± 10.25	<0.0001*

Comparison of medication adherence



Comparison of medication adherence

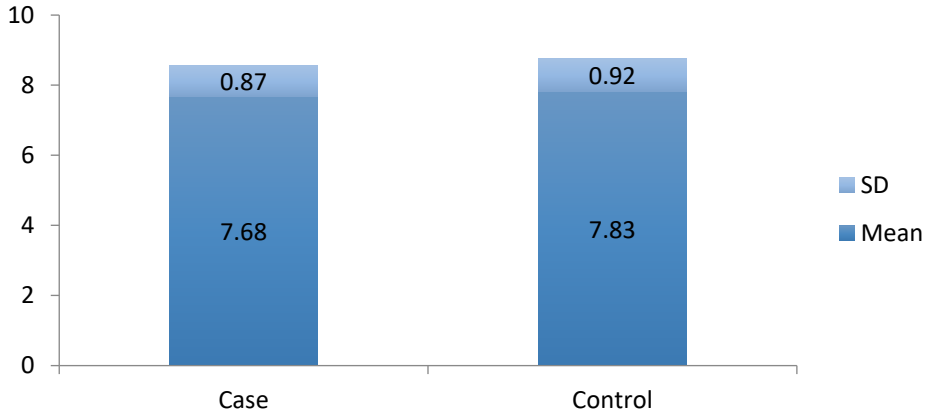
Glycemic control: No statistically significant difference in HbA1c at study completion (p>0.05)

Comparison of HbA1c Levels

The mean HbA1c level among app case group was 7.68 ± 0.87%, while it was 7.83 ± 0.92% among control group. The difference in HbA1c levels was not statistically significant (P = 0.5143), indicating similar levels of long-term glycemic levels in both groups.

	Case	Control	P Value
HbA1c (%)	7.68 ± 0.87	7.83 ± 0.92	0.5143

Comparison of HbA1c Levels



Comparison of HbA1c Levels

No serious adverse events related to app usage were reported.

DISCUSSION

The mobile application significantly improved DFU outcomes, likely due to enhanced patient engagement, better adherence, and prompt clinical feedback. Continuous visual documentation allowed early detection of deterioration, enabling timely intervention. The improvement in adherence may also have contributed to faster healing rates.

These findings align with global trends showing mHealth interventions improve chronic disease outcomes, but this study provides DFU-specific evidence from an Indian population. Limitations include single-center design, small sample size, and short follow-up.

Harish et al., study on a patient-owned wound surveillance system for DFU care demonstrated that 80% of participants achieved wound healing within an average of 9.5 ± 8.2 weeks. The study highlighted the app's capability to detect wound deterioration before clinical evaluation, underscoring the importance of continuous monitoring in promoting timely medical responses and improved healing outcomes. **Ploderer et al.,** conducted a research on the MyFootCare mobile application revealed that patients found the app's ulcer size tracking feature beneficial for monitoring their DFU progress. This functionality enabled

patients to engage more effectively in self-care practices, potentially leading to better wound management and faster healing.

CONCLUSION:

This study proved that the application of a mobile-based smartphone app improved clinical outcomes significantly in patients with diabetic foot ulcers. App users had an increased rate of healing of ulcers, lower healing time, and improved drug compliance compared to the control group receiving conventional care. While glycemic control (HbA1c) and baseline characteristics were comparable between groups, the intervention group had superior wound outcomes, which are probably attributed to frequent monitoring, prompt communication, and enhanced patient engagement made possible by the app. These results indicate that digital health interventions can be a useful adjunct in chronic wound care, especially in diabetic patients.

Declarations
Ethical Approval: Approved by Institutional Ethics Committee, Saveetha Medical College and Hospital.
Funding: None.
Conflict of Interest: None declared.
Acknowledgements: The authors thank the patients and clinical staff for their participation and support.

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