Research Square

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Platelet-Rich Plasma Versus Honey in the Treatment of Diabetic Foot Ulcers: A Quasi-Experimental Study

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Abstract

Background: Diabetic foot ulcers are common complications of diabetes, and if improperly managed, they result in loss of function or even life. This study aimed to assess the feasibility of using platelet-rich plasma in resource-limited settings and compare its outcomes with those of honey/saline dressing.

Methods: The participants were followed for a duration of 8 weeks to determine patient satisfaction, reduction in wound area, and occurrence of wound complications. Study variables were collected in a Microsoft Excel sheet, and analysis was done using SPSS version 25. Mann–Whitney U test and a t-test were used to estimate the feasibility attributable to the intervention. A p-value <0.05 was considered statistically significant.

Results: 38 participants were enrolled (20 PRP, 18 honey). Baseline demographic and clinical characteristics were comparable between groups. The PRP group demonstrated higher median wound-healing rates at both 4 and 8weeks compared with the honey group. Healing outcomes did not differ by sex, smoking status, or comorbidity. Infection rates were similar between groups (30.0% vs. 33.3%, p = 0.825). Overall, PRP patients scored an average of 9.7 points higher on patient-reported outcomes than honey patients across assessments (78.99 vs. 69.32; 95% CI 8.1–11.2; p < 0.001). Both groups improved between weeks 4 and 8, but PRP showed greater gains across most domains.

Conclusions: These findings support PRP as a more effective modality for managing chronic wounds than honey/ saline, though larger trials are warranted to confirm long-term outcomes and cost-effectiveness.

Introduction

Wounds present a complex challenge for both healthcare providers and patients as it is one of the most common reasons for delayed hospital discharge and/or increased healthcare spending (1, 2). Wounds are classified in a variety of ways including the degree of contamination (clean, clean-contaminated, contaminated and dirty) and also based on the underlying disease (e.g. diabetic wounds, venous wounds, pressure ulcers trauma wounds etc.) (3, 4). Wounds can also be classified as acute or chronic, though there is no agreement or recognized distinction between acute and chronic wounds or a clear pre-established consensus for chronicity (5). Generally, wounds that have failed to heal within 2–3 months are termed as chronic wounds (6, 7).

The estimated global prevalence of chronic wounds in the general population is 1.5–2.21 per 1000 population (5, 8). Patients with chronic wounds tend to be older, have chronic disease (such as diabetes), non-ambulatory or unable to provide self-care (9, 10). Chronic wounds such as diabetic wounds are associated with depression, anxiety, functional impairment and reduced quality of life for both patients and caregivers (9–11). Furthermore, over 85% of lower limb amputations are preceded by foot ulcers and diabetes remains a major cause of non-traumatic amputations globally (9, 12).

There is an expected increase in chronic wounds due to increase in the elderly population and increased incidence of metabolic diseases such as diabetes (11, 12). To reduce this increasing incidence, a focus needs to be placed on public education and intervention to decrease the growing population of people with comorbid conditions. However, for those who already have the comorbid conditions, the focus needs to be placed on prevention of complications such as diabetic and pressure ulcers. And for those who have already developed these complications the focus of care has to be on controlling factors related to wound healing and using the effective wound dressing method in order to prevent loss of function, loss of limb and loss of life.

Diabetes is an increasing public health concern globally and the burden of diabetic foot disease is expected to increase with the increasing prevalence of type 2 diabetes(13, 14). Globally, 3–10% of people with diabetes have a foot ulcer, though studies in Africa have shown higher prevalences between 4–19%(13, 14). Studies done in Tanzania have reported prevalence of diabetic foot ulcer (DFU) between 3.2%-15%(13–15). With the projected increase in prevalence of DFU among diabetics, it is imperative that cost effective wound dressing methods are developed especially in resource limited settings.

More than 5000 dressing methods have been described in literature including tulle dressings, activated charcoal, normal saline, honey, wine, foams, hydrocolloids, bioactive dressings, and recently, platelet rich plasma (PRP), but there is yet an ideal wound dressing method (2, 16, 17). Autologous PRP is one of the most recently developed treatment modalities that has shown a lot of promise since its inception 3 decades ago, but yet adoption of this strategy is still a challenge to most (18). Autologous platelet-rich plasma (PRP) is a product derived from blood that is increasingly being used in clinical practice and, among other applications, it has become an alternative to the dressings for various wounds/ulcers (2, 17–20). The curative properties of PRP rely on the fact that platelets are a physiological reservoir of growth factors, which have an active role in tissue regeneration (1, 16, 18, 19). It is well known that platelets contain a great variety of growth factors with healing functions such as platelet derived growth factor, vascular endothelial growth factor, transforming growth factor-β, fibroblast growth factor, epidermal growth factors, insulin-like growth factor-1 and some cytokines stored in alpha granules (1, 16, 18, 19).

Autologous PRP has been used in treatment of several different kinds of wounds. A number of studies have investigated the efficacy of autologous PRP in diabetic wounds and the results have been varied, with most of these studies showing improved wound healing in patients treated with PRP, while other few studies showing no difference (2, 17–20). We have found few of these studies (n = 4) to be in Africa and none are in Sub-Saharan Africa from a search done on PubMed in December 2023 (21–24).

In this study we aimed to analyze the efficacy of autologous PRP in the treatment of diabetic foot ulcers/wounds. Our hypothesis was that after 8weeks of treatment, patients treated with PRP will have at least 50% reduction in the ulcer/wound area and have better patient satisfaction compared to honey/normal saline dressing.

Methods

Study design

A quasi-experimental study including patients presenting to Arusha Lutheran Medical Centre (ALMC), Arusha, Tanzania, between August 2024 – April 2025 was done. This study assessed the feasibility of using Platelet-Rich Plasma in diabetic wounds, assessing the safety and patient satisfaction and compare it with other dressing methods currently in use (honey or normal saline).

Study areas

Arusha Lutheran Medical Centre (ALMC) is a zonal referral level hospital in Arusha city, Arusha region, Tanzania. It has a 200-bed capacity. It serves as a general surgery training site for COSECSA (College of Surgeons, East, Central and Southern Africa) and largely serves an urban population.

Study population

Inclusion criteria

- Wounds that are > 1mo.
- Signed informed consent to participate

Exclusion criteria

- Current history of malignancy, pregnancy, breastfeeding or chronic kidney disease on dialysis
- Chemotherapy or radiotherapy within 3mo of study.
- Patients with hemoglobin <8g/dl (or hematocrit < 20%), low serum albumin level <2gm/dl, low platelet count < 100,000/mm^3, HIV, and chronic infectious diseases at the beginning of the study.
- Patients with bleeding disorders or using anticoagulants.

Recruitment

Patients were recruited by one of the members of the research team (lead investigator or research assistants). When eligible patients were identified, possibility of their inclusion into the study was explained and if they agreed to participate, they signed a consent form and included in the study. The patients were allocated to group A (dressing with platelet rich plasma) or group B (dressing with honey/normal saline) without randomization. Full detailed history and physical examination of the wound was done. Lab investigations including full blood picture, random blood glucose, HbA1c, kidney (creatinine) and liver function (Serum albumin and aspartate transferase) tests were taken at the beginning of the study.

Protocol for PRP Preparation and Dressing

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Following aseptic methods, 20 ml of venous blood was taken from a peripheral vein and anticoagulated by acid citrate dextrose. PRP was prepared by double centrifugation method using Hettich Universal 16 centrifuge machine (Andreas Hettich GmbH & Co. KG, Tuttlingen, Germany). The first spin used was a hard spin (5000 rpm for 15 minutes) which separates the blood into three layers: Plasma, buffy coat and red blood cells. The plasma and buffy coat were then be aspirated into a sterile test tube without an anticoagulant and subjected to a second spin (2000 rpm for 5 minutes). The second spin (soft spin) allowed the precipitation of the platelets to fall onto the bottom of the tube. 2–5 mls of PRP were aspirated depending on the wound size and activated with 10% calcium chloride (0.3 ml for 1 ml of PRP). The unused part of the blood was discarded following the laboratory's protocol and the PRP preparation was transported immediately in a safety container to the patient ready for application.

This preparation was then be applied on the ulcer and the wound covered by sterile gauze. Before application of the PRP on the wound, the wound was cleaned with normal saline as per standard treatment protocol. Patients received wound care every seven days with autologous PRP, based on the estimated mean lifespan of platelets (7–10 days). The treatment with autologous PRP was performed by the investigators (see Figs. 1 and 2).

Also, patient satisfaction was assessed on a weekly basis using WOUND Q-score. The first treatment session of the study was performed on day 0, and the data was recorded in the patient medical record. From this point onwards, data was collected every 7 days for 4–8 weeks. The WOUND-Q score is an instrument used to measure 13 independent scales on 4 domains; wound characteristics, health related quality of life, experience of care and wound treatment (25). It is a validated tool meeting COSMIN standards for good psychometric properties, and one of few patient-reported outcome measures used in chronic wounds (26).

Sample size

Based on the primary end point of the study (percent reduction in the ulcer size at 4weeks) and in light of previous studies done in Africa (13, 21). We assumed the prevalence of diabetic foot ulcer is 3.2% based on the study done in Tanzania by Chalya et al., (13), the estimated sample size was 48 patients. The calculation were based on http://calculator.net/sample-size-calculator.html, and considering a 95% confidence interval and a margin of error of 5%.

Convenience sampling method was used, whereby all patients presenting with diabetic foot ulcers to the outpatient clinic or the inpatient service, were approached for enrollment into the study. Convenience sampling was selected because we assumed a low prevalence of DFU in our setting (3.2%, Chalya et al.,).

Data Management

Data was collected from patient history during clinical clerkship, direct wound measurements and laboratory tests. Electronic case report forms (data collection form) were used to document data on a weekly basis. Measurements of wound size were performed using the smartphone based digital planimetry application, imitoMeasure® (imito AG, Zurich, Switzerland).

Data was entered into a secure electronic database (Microsoft Excel). Double data entry was employed to minimize errors. Access was restricted to authorized personnel and personal identifiers were not be stored to maintain confidentiality.

Statistical analysis

The categorical variables were presented as frequencies and percentages and continuous variables using measures of central tendency and dispersion (mean and standard deviation for normally distributed variables, and otherwise median and interquartile range). Using either the t-test (for parametric data) and the Wilcoxon signed rank test (non-parametric data), we estimated the mean WOUND-Q scores before and after treatment. The analysis of the efficacy was carried out on an intention-to-treat basis by comparing the percent reduction in wound area after 4 and 8 weeks of treatment, with respect to baseline. Using the Mann–Whitney U non-parametric test, we estimated the effect attributable to the intervention. Subsequently, in order to adjust the comparisons for the baseline measurements, we carried out covariance analysis models. As well as adjusting for baseline, we adjusted for the potential confounding or effect-modifying covariates. A p value < 0.05 was considered statistically significant. Complications resulting from treatment was assessed using descriptive statistics (frequency and percentages). All the analyses were performed using SPSS version 25 statistical software.

Legal and ethical issues

This research project was carried out in accordance with the principles of the Declaration of Helsinki and in compliance with current legislation on medical research. Prior to carrying out the study, approval was obtained from the Institution Review Board of National Institute for Medical Research (NIMR/HQ/R.8a/Vol.IX/4672), as well as consent from the participating patients, guaranteeing that the anonymity and confidentiality of the data collected was safeguarded.

Results

A total of 38 participants were enrolled, with 20 in the Platelet-Rich Plasma (PRP) group and 18 in the honey group.

Baseline Characteristics

The two groups were similar in baseline demographic and clinical variables (Table 1). There were no statistically significant differences in age, duration of diabetes mellitus, wound duration, white blood cell count, or hemoglobin concentration. The male-to-female ratio did not differ significantly (60.0% vs. 38.9% male, p = 0.194). Smoking prevalence was significantly higher in the PRP group (40.0% vs. 11.1%, p = 0.043)

Table 1
Baseline characteristics of study participants.

Variable	PRP Mean ± SD	Honey Mean ± SD	p-value
Age (years)	55.00 ± 6.67	55.78 ± 6.86	0.725
Male*	60.0	38.9	0.194
Smokers*	40.0	11.1	0.043
DM Duration (yrs)	12.50 ± 5.05	12.28 ± 3.30	0.875
Wound Duration (weeks)	6.00 ± 2.41	6.06 ± 2.51	0.945
WBC (x10⁹/L)	7.87 ± 2.60	7.48 ± 2.12	0.62
Hemoglobin (g/dL)	10.27 ± 1.71	10.66 ± 1.70	0.279
FBG (mmol/L)**	8.7 (7.55–11.93)	9.8 (7.1-11.65)	0.895
HbA1c (%)**	8.6 (7.7–9.5)	9.15 (8.25–9.53)	0.388
Platelet count (x10^9/L)**	324 (254-361.75)	308 (208-365.50)	0.559

* We used percentages for these data. ** Median and interquartile range was used for these values due to their skewed distribution.

Wound Healing and Complication Rates

At week 4, the PRP group had a significantly higher median healing rate than the honey group (41.24% vs. 23.64%, p < 0.001). At week 8, PRP continued to show superior healing rates (65.82% vs. 44.29%, p < 0.001) (Table 2).

Mann–Whitney U tests showed no significant difference in healing rates at weeks 4 or 8 by sex (p = 0.204), smoking status (p = 0.119 and p = 0.289), or hypertension status (p = 0.193 and p = 0.183). There was no significant difference was found in infection rates between groups (30.0% vs. 33.3%, p = 0.825), and no ischemia occurred in either group.

Table 2
Wound healing rates at week 4 and week 8.

Time Point	PRP Median (IQR)	Honey Median (IQR)	p-value
Week 4	41.24 (31.29–52.39)	23.64 (31.29–52.39)	< 0.001
Week 8	65.82 (52.44–80.89)	44.29 (52.44–80.89)	< 0.001

Correlation Analyses

Pearson's correlation analysis showed that week 8 healing rate correlated positively with hemoglobin concentration (r = 0.325, p = 0.047). Furthermore, fasting blood glucose was positively correlated with HbA1c (r = 0.322, p = 0.049), further supporting control of FBG to improve overall diabetes control. Spearman's rank correlation showed a positive relationship between wound duration and diabetes mellitus duration (ρ = 0.339, p = 0.037), also supporting the evidence of occurrence of DFUs in patients with longstanding history of diabetes.

Overall Wound-Q Changes (Patient Satisfaction)

A repeated-measures General Linear Model (GLM) was used to evaluate differences between groups, across time, and among wound-Q subscales.

There were significant effects of time (F = 29,238, $p < 0.001$, $\eta^2 = .999$), group (F = 160.3, $p < 0.001$, $\eta^2 = .817$), and subscale (F = 29.0, $p < 0.001$). Significant interactions were observed for time × group (F = 2234.5, $p < 0.001$, $\eta^2 = .984$), subscale × group (F = 9.93, $p < 0.001$, $\eta^2 = .786$), and time × subscale × group (F = 125.96, $p < 0.001$, $\eta^2 = .778$), indicating that the magnitude of improvement differed between PRP and Honey depending on the wound-Q domain. PRP patients scored on average 9.7 points higher than Honey patients across assessments (PRP: 78.99, Honey: 69.32; 95% CI: 8.1–11.2, $p < 0.001$).

Improvements were seen in both groups between week 4 and week 8 across most wound-Q subscales. For the PRP group, significant increases were observed in assessment, drainage, smell, lifestyle, psychology, sleep, social, dressing, and overall wound-Q (all $p < 0.001$). No significant change was seen in information, team, or staff domains. Similar patterns of improvement were seen in the Honey group, though of smaller magnitude, with no significant changes in information, team, or staff.

Independent-samples t-tests supported the GLM results. At week 4, PRP patients had significantly higher scores than Honey in nearly all domains, particularly drainage (75.4 vs 57.6), smell (71.6 vs 60.3), and dressing (79.6 vs 70.2; all $p < 0.001$). At week 8, these differences persisted, with PRP maintaining higher scores across most domains (overall wound-Q: 79.9 vs 69.9; $p < 0.001$).

Discussion

Platelet Rich Plasma has the potential to drastically improve the outcome of chronic wounds such as diabetic wounds and thus decrease the morbidity and expenditure associated with such wounds. In this

current study, we aimed to compare the efficacy of using PRP versus honey/normal saline in the treatment of diabetic foot wounds and also to assess the feasibility of using PRP by assessing WOUND-Q scores as well as interviewing stakeholders. We used honey and normal saline for dressing due to their local availability and reduced costs as compared to other methods of wound dressing such as activated charcoal and VAC which though effective are more expensive.

Several studies done on diabetic foot ulcers, have reported better efficacy of wound treatment with PRP compared to other methods. For example, Xie et al., in China compared PRP and 0.1%rivanor(2-ethoxy-6,9-aminoacridinelactate) gauze and found that PRP had higher closure rates at 4weeks compared to the control group (27). Patients in the PRP arm also had shorter hospital stays (19.36+/-7.239 d vs 48.13+/-11.721 d, $p < 0.05$) and lower total hospital expenses (2.48+/-0.45 ten thousand yuan and 5.63+/-1.35 ten-thousand-yuan, $p < 0.05$) (27). El-Mabood and Ali in Egypt have reported PRP to have 50% higher healing rates (97.5%) at 12 weeks compared to betadine dressing (82.5%) with fewer complications, wound infection (17.5% vs 27.5%), pain (32.5% vs 62.5%) and failed healing (2.5% vs 17.5%) (28). Another study, conducted in Egypt by Salem and Tawfik, also reported efficacy of PRP compared to moist dressing (29). They found 97.6% of patients with PRP treatment had complete healing at 3weeks compared to 93.5% of patients treated with moist dressing who had complete healing at 8weeks (29). We have found one study from Sub-Saharan Africa (Kenya) investigating the use of platelet rich plasma dressing for chronic wound management versus autologous fat graft (30).

These results of individual studies have also been corroborated with systematic reviews of randomized controlled trials. Three such studies include a systematic review with meta-analysis of randomized controlled trials by Li et al., assessing efficacy and safety of PRP dressings in chronic wounds, has shown PRP to have significantly higher complete wound healing rate compared to saline dressing at 8 and 12 weeks (OR = 11.70; 95%CI, 1.40 to 97.97; $p = 0.02$) with similar rates of infection (OR = 0.53; 95%CI 0.20–1.44, $p = 0.21$) (19).

This is in agreement with another systematic review and meta-analysis of randomized controlled trials on patients with diabetic foot ulcers that has reported PRP to result in higher healing rate (RR = 1.42, 95% CI 1.30–1.56, $p < 0.001$), reduced healing time (MD = − 3.13, 95% CI − 5.86 to − 0.39, $p < 0.001$), decreased rates of amputation (RR = 0.35, 95% CI 0.15–0.83, $P < 0.001$) and has similar adverse effects (RR = 0.96, 95% CI 0.57–1.61, $p > 0.05$) as compared to other dressing methods (31). Also, in agreement with the above 2 meta-analysis, another systematic review and meta-analysis of latest randomized controlled trials assessing efficacy of PRP as therapy for DFU was done by Syafira et al., (32). They have reported PRP exhibited a healing rate that was twice as high as the control group (Relative Effects (REs) = 2.338; 95% CI 1.056–1.857, $p = 0.019$), the healing time was shortened by 2 days (REs =-2.815; 95% CI =-3.252 to-0.576, $P = 0.005$), and there was a difference of 0.482 cm^2 in the reduction of ulcer area between the two groups (REs = 0.482; 95% CI =-2.428 to 4.002, $P = 0.630$) (32). None of the included Randomized Controlled Trials (RCT) studies reported any adverse events in the PRP group (32).

We have uncovered few studies that have compared the quality of life between patients treated with platelet rich plasma (PRP) and other methods of wound dressing such as honey. However, there are several studies that have reported on the health-related quality of life among patients with chronic wounds. Simonsen et al., noted that wounds with drainage, diabetic wounds, longer duration of disease, smell and sleep interference were associated with poor WOUND-Q scores (33). This would support our findings whereby patients treated with PRP had less drainage and decreased wound dressing time and thus resulting in better WOUND-Q scores. Also similar to our study, a study done in India by Devesvar et al., reported that patients treated with PRP had reduced pain and higher quality of life improvements as compared to patients treated with other methods (PDGF gel and normal saline) (34).

Conclusion

Baseline demographics and laboratory parameters were comparable between treatment groups. PRP significantly improved wound healing rates at both week 4 and week 8 compared to honey, while infection, ischemia, and sex distribution did not differ significantly. Smoking was more common in the PRP group. Certain baseline variables, including HbA1c, WBC, platelet count, and hemoglobin, showed significant correlations with each other and with healing outcomes.

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Figures

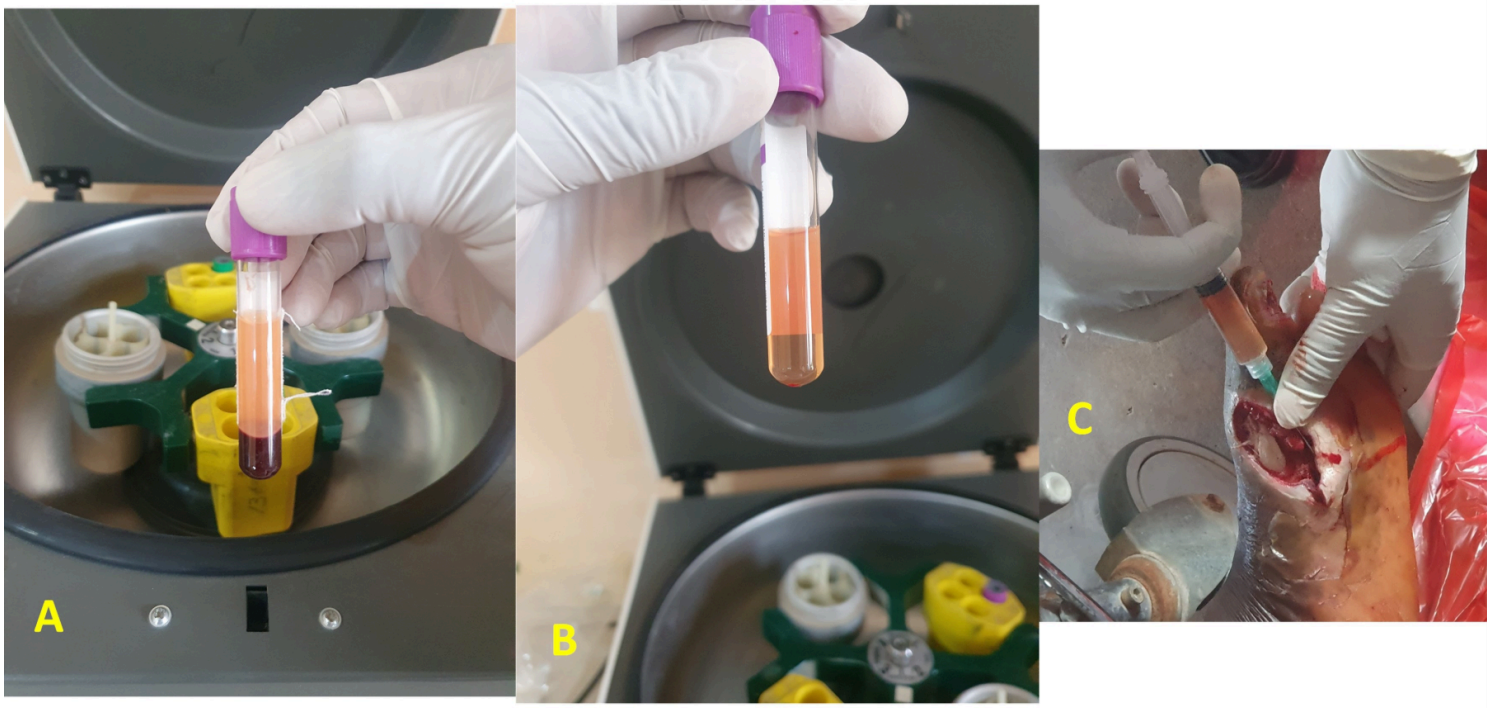


Figure 1

A – After the first centrifuge, B – after the second centrifuge, C – Injection of the PRP (topical application though not shown was also done).

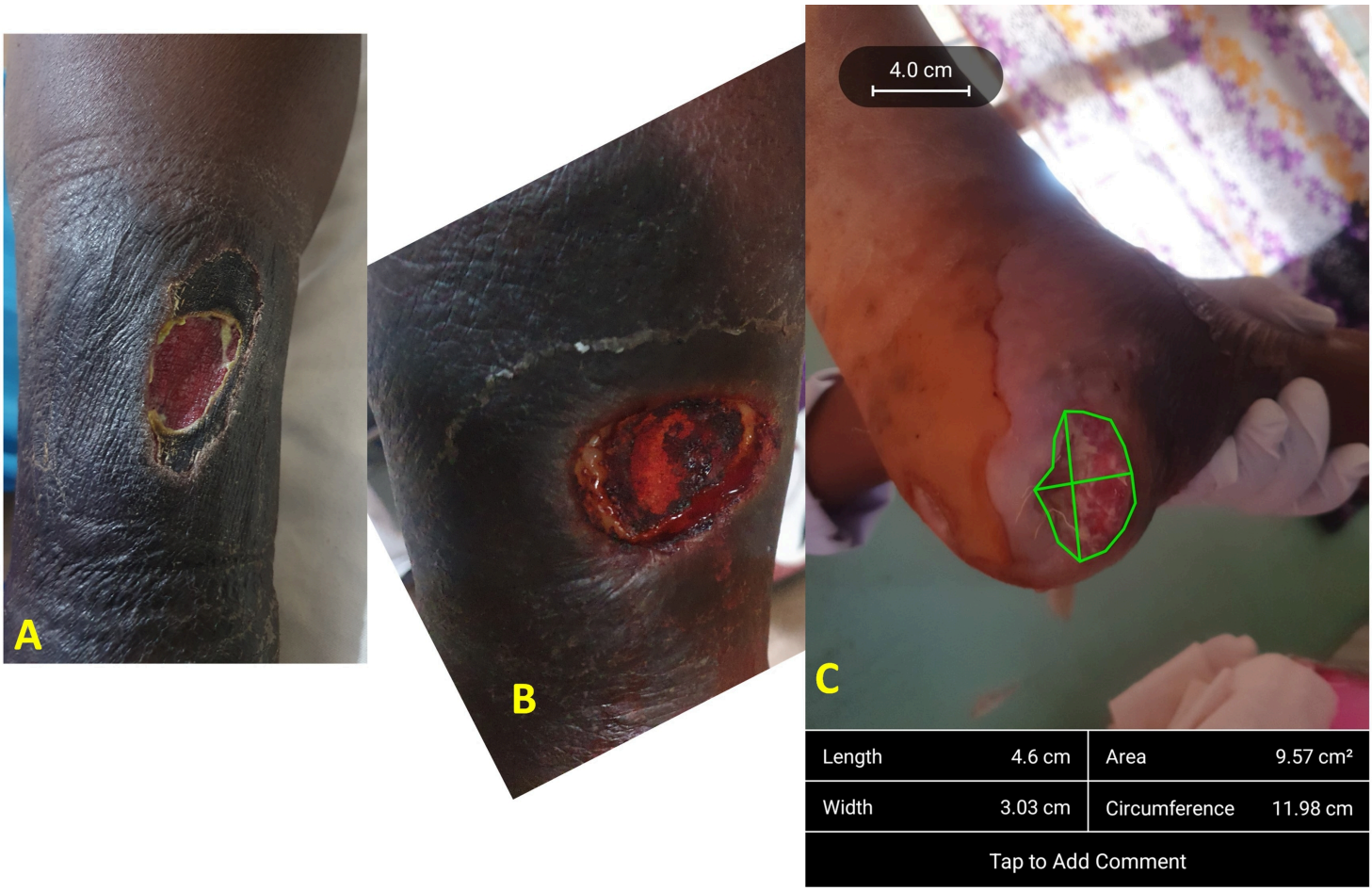


Figure 2

A – wound before debridement (removal of the dark eschar). B – 4 weeks after application of the PRP. C – How wounds were measured using imitoMeasure®.