Efficacy of Platelet-Rich Plasma in Chronic Wounds

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Abstract

Chronic wounds are responsible for exorbitant healthcare costs, poor quality of life, and increased likelihood of associated systemic complications. Platelet-rich plasma is derived from human blood and contains regenerative growth factors that have been proven to promote healing in dermatology, aesthetics, and wounds, more often in traditional care settings. A quality improvement project was implemented to determine if platelet-rich plasma is an effective treatment option for chronic wounds in the mobile setting. All participants voluntarily signed informed consent. Data was collected on three participants (n = 3). The project took place within a mobile clinic that treats patients in their personal residences. All participants had a single wound treated with platelet-rich plasma per the clinic's protocol for five weeks. The Bates-Jensen Wound Assessment Tool is a valid and reliable tool that was completed at day one, week three, and week six to determine if wound health had progressed with platelet-rich plasma treatments. At the end of project, one wound completely healed, one wound scored significantly lower on the Bates-Jensen Wound Assessment Tool, and one wound worsened with an increased score. Descriptive statistics were used to analyze data. Overall, platelet-rich plasma proves to be a promising treatment for chronic wounds in the mobile setting. Mobile clinics can benefit from performing platelet-rich plasma treatments on chronic wounds as it decreases wound size and improves healing time, which improves patients' quality of life and decreases complications and healthcare costs.

Keywords: platelet-rich plasma, chronic wounds, wound care, healing time, wound size, mobile wound care

Efficacy of Platelet-Rich Plasma in Chronic Wounds

Wound care is often overlooked and would benefit from more robust literature to guide practice. Ineffective wound care drives up healthcare costs and negatively affects patients with chronic wounds. There is an urgent need to determine which wound products are most useful for wounds of different stages and types. Exploring the efficacy of wound products can turn patients' lives around while aiding in relieving the burden on the healthcare system.

Problem Statement

The increasing cost of healthcare is an ongoing problem in the United States (US). Chronic wounds and poor outcomes are partially responsible for the rising expenditure. Medicare has determined that wound care and treatment costs will soon be responsible for between $28.1 billion and $96.8 billion (Sen, 2019). Positive wound outcomes will help reduce healthcare costs. Not only do ineffective wound care and treatments adversely affect the cost, but they also negatively impact patient outcomes and quality of life (QoL). Individuals with chronic wounds have decreased QoL due to the toll wounds take on physical and emotional well-being (Mahmoudi & Gould, 2020; Vogt et al., 2020). Chronic wounds do not close within one month, do not undergo the proper healing process, and are frequently correlated with underlying comorbidities that complicate healing (Sen, 2019; Sen, 2021). Wound-related complications are always possible, keeping the cycle in perpetual motion. The Institute for Healthcare Improvement (IHI) Triple Aim is a national initiative emphasizing three elements: improving patient care satisfaction, improving population health, and reducing healthcare costs (IHI, n.d.-b). Improving chronic wound outcomes directly aligns with the IHI Triple Aim initiative because it improves patients' QoL and reduces healthcare costs in the US. Part of the problem is that chronic and complex wounds need to heal completely. There is a shortcoming of powerful

clinical research results that have meaning and applicability to practice (Mahmoudi & Gould, 2020). Platelet-rich plasma (PRP) is a reasonably new treatment used on chronic wounds, and the lack of current research regarding efficacy complicates treatment plans for wound care providers. Exploring the benefits of PRP on chronic wounds could be groundbreaking for the world of wound care.

Purpose and Rationale

Determining the efficacy of PRP for chronic wounds in the mobile setting will provide meaningful information for wound care providers and evidence to guide practice. In turn, improved or successful wound closure will improve patient outcomes, decrease associated complications, lower healthcare costs, and improve patients' QoL. While the current focus is on wound care, the same principles can be translated to other realms of healthcare to produce similar outcomes that positively impact patients, healthcare, and the US economy. Not only will discovering the efficacy of PRP improve patients' lives, but it will also help close the gap between evidence and practice while treating the patient holistically. This paper explores how PRP improves wound care, how its efficacy benefits patient outcomes, and how the doctoral project will test efficacy in an unprecedented setting.

Background and Significance

Wound care for chronic wounds is expansive and fluid, and there is a lack of literature surrounding clinical practice guidelines, standard protocols, and the efficacy of products and therapies. Wound outcomes are determined by wound size and healing time, while patients' reports on the QoL and overall satisfaction are also factors (Eriksson et al., 2022; Monaco et al., 2021). Innovative products have the potential to improve wound outcomes. Dermatology, aesthetics, and regenerative medicine use PRP because of its robust growth factors, proteins,

cytokines, and peptides that promote skin and tissue regeneration (Samadi et al., 2018). However, there is limited clinical research on using PRP on chronic wounds particularly in mobile clinics.

Patients with Chronic Wounds

Certain patients are at higher risk for developing chronic wounds and impaired healing. Diabetes, obesity, malnutrition, impaired mobility, and older age increase patients' risks for chronic wounds and complications (Evans & Kim, 2022; Sen, 2019; Wernick et al., 2022). Managing and preventing risks can potentially improve wound progression and healing time. For example, controlling glucose, weight loss, increasing protein intake, and frequent repositioning can assist wounds in healing. Chronic wounds have little to no improvement within four to 12 weeks (Cho et al., 2020). There are many complications with chronic wounds, which include infection, sepsis, osteomyelitis, and electrolyte imbalance (WoundSource, 2018). With chronic, non-healing wounds and potential complications, patients will likely spend more on wound care and treatments and risk QoL due to lifestyle changes necessary to accommodate the wounds. In one study, authors found that chronic wound patients scored below the global average on two different quality-of-life instruments due to unsightliness, malodor, and restriction of daily activities (Vogt et al., 2020). Another study confirmed that QoL was lowest for patients with chronic wounds and associated amputations, as the wounds affect physical functionality, emotional health, and mental health (Olsson et al., 2019). Wound type, stage, patient history, and risk factors are all considerations when determining appropriate management and treatment. Patient-centered wound care is imperative in treating wounds, and in one study, results showed that it leads to more satisfied and educated patients and improved QoL (Gethin et al., 2020).

Efficacy of Platelet-Rich Plasma

Wound care uses various products depending on the wound's type, stage, and complexity, some of which are more effective than others. It is common for providers to frequently change wound products and dressing types depending on the progression or regression of the wounds. It is crucial to assess the entirety of the patient as patients' bodies may react better to particular products. For example, allergies and nutritional status may affect the choice of product type and dressings. Some standard wound products include topical antibiotics, chemical debriding products, and a variety of skin substitutes (Armstrong & Meyr, 2022; Bowers & Franco, 2020). Wound products and treatments are ever-changing and require more scientific research to prove efficacy. In a study comparing PRP gel with standard saline dressings for diabetic foot wounds (DFU), results showed that the PRP group had a reduction in wound size and shorter wound healing time (Elsaid et al., 2019). Another study exploring the use of PRP on tendon-exposed wounds resulted in decreased scores on two scar scales, a lack of erythema and edema, and improved size and staging of the wounds (Deng et al., 2022). Not only does PRP have a higher likelihood of treating stubborn ulcers, but it is also easy to collect (Xia et al., 2019). Since wound care is often trial-and-error, it is essential to retrospectively analyze the efficacy of the PRP data to determine if PRP should become standard practice for chronic wounds. Not only does the data prove efficacy, but it also provides evidence to guide clinical practice.

Current Practice

There is a need for more robust, current literature supporting clinical guidelines for chronic wound care. Ausmed (2023) provides a comprehensive guide to wound care practice, including wound assessment, dressings for different types of wounds, wound healing, and cleansing and debridement recommendations with graphics. During an extensive literature

review, this was the only current guideline found. Many other sources provide generic recommendations for wound care that list products, procedures, and dressings as they could apply to multiple wound types and stages, prolonging the healing process. Chronic wounds depend on each individual requiring personalized treatments in order to maximize successful healing (Laurano et al., 2022). Learning more about specific wound products and their efficacy could aid in developing guideline updates.

Improving Wound Outcomes

The ultimate goal for chronic wound care is to have wounds close and heal promptly. However, in some instances, wound closure is impossible, so managing symptoms and preventing regression and complications is essential. With multiple therapies in wound care providers' practice, it is difficult to determine which are most effective. Laurano et al. (2022) reviewed the literature to explore several wound products, dressing types, and efficacy as presented in randomized clinical trials. There is a clear gap between the literature and clinical practice. The inability to incorporate evidence in clinical practice leads to substandard care and sacrifices patient safety (Gardner, 2023). The gap is partly due to the need for clinical research on specific wound products and therapies. Laurano et al. (2022) revealed the gap between research and commercial wound products. Determining which products are most effective will increase the amount of evidence-based literature to guide practice and, in turn, improve wound outcomes. Improving wound outcomes will also reduce healthcare costs and enhance patients' QoL. While the goal is to discover which products effectively improve wound outcomes, the benefits are expansive across healthcare.

Common Themes

A thorough literature review simultaneously exposed chronic wounds' burden on individuals and the US (Bowers & Franco, 2020; Laurano et al., 2022; Sen, 2019; Sen, 2021; Vogt, 2020). The lack of literature specifying effective treatments for chronic wounds in conjunction with minimal clinical guidelines creates dilemmas for wound care providers. Various comorbidities delay healing and put patients at risk for chronic wound complications (Joszt, 2021; WoundSource, 2018). Providers must use judgment when creating care plans and make adjustments as needed with little evidence to support decisions. More literature must study specific wound products' efficacy to close the gap between literature and clinical practice.

Internal Data

In a mobile wound care organization in the southwestern US, clinic staff has recognized a need for innovative and effective wound care treatments for chronic wounds. The organization serves primarily geriatric patients with chronic wounds, and providers perform wound care in patients' homes, group homes, and skilled nursing facilities (SNFs). Providers are passionate about giving comprehensive care, teaming up with caregivers, and coordinating interdisciplinary care. The organization has relationships with vendors who want providers to trial new products, such as PRP, on chronic wounds to determine the products' efficacy in this unique setting. Analyzing PRP-specific data will substantiate efficacy and guide practice based on evidence. The data will influence the organization's decision-making and contribute to the literature other wound care providers can reference.

PICOT Question

Current literature regarding PRP treatment proves there are many benefits and few risks. With the organization eager to discover innovative treatments for chronic wounds, it is crucial to

determine the efficacy of PRP among their patient population. Per current research and the organization's demands, the following PICOT question is presented: In patients with chronic wounds (P), how does platelet-rich plasma therapy (I), compared to current wound therapy (C), affect wound healing (O) within six weeks of implementation (T)?

Search Strategy

Three databases produced current literature regarding the PICOT question, which included Cumulated Index to Nursing and Allied Health Literature (CINAHL), Cochrane Review, and PubMed. The three databases are reputable because they provide credible, peer-reviewed articles related to nursing and healthcare. The database searches included similar keywords and phrases, and abstracts confirmed which studies were most applicable and relevant.

Database searches used various keyword combinations related to the PICOT question. For the population, terms such as *chronic wounds*, *non-healing wounds*, *pressure ulcers*, *pressure wounds*, and *diabetic wounds* produced substantial results. Keywords for the intervention included *platelet-rich plasma*, *PRP*, *protein-rich plasma*, *protein-rich plasma wound care*, and *protein-rich plasma uses*. *Standard wound care* and *advanced wound care* generated comparisons to the intervention. The search for outcomes narrowed when keywords included *efficacy*, *benefits*, *wound outcomes*, *wound healing*, and *wound closure*. Boolean expressions made database searches more efficient. Each database used different keyword combinations and produced numerous search results.

Initial and Final Search Yields

All three databases produced varying search yields. The initial CINAHL search yielded 255 articles using the following keywords: *wounds*, *chronic wounds*, *pressure ulcers*, *pressure wounds*, *PRP*, *plasma-rich protein*, *efficacy*, *benefits*, and *outcomes*. The search presented 47

articles *after adding non-healing wounds* and *effectiveness*. The Cochrane Review search used combinations of the previous keywords. However, adding *wound treatments*, *wound management*, *chronic wound patients*, *complex wounds*, *wound healing*, and *wound closure* yielded 2,549 articles; this search did not include terms related to the intervention. The search was narrowed to 283 articles when the keywords were broader, and the intervention terms were applied. The PubMed search process was similar to the other two databases and initially yielded 615 articles, and the final search produced 145 articles.

Limitations, Inclusion, and Exclusion Criteria

After the final search yields produced hundreds of articles, inclusion and exclusion criteria were applied. Search filters included academic and peer-reviewed journals printed in English and published between 2018 and 2023. Abstracts determined applicability to the PICOT question. A total of 20 articles underwent rapid critical appraisal, and ten studies underwent thorough evaluation. Studies with small sample sizes were excluded. The ten studies include four meta-analyses and systematic reviews, three randomized controlled trials (RCT), one quantitative preliminary study, one quantitative cross-sectional study, and one case-control study (Appendix A). Searching the gray literature provided generalized information about chronic wounds, staging, standard wound care, and related cost disparities. An ancestral search was not performed.

Critical Appraisal and Synthesis of Evidence

All research studies were evaluated using rapid critical appraisal to determine validity and reliability and, eventually, their application to practice (Melnyk & Fineout-Overholt, 2019). A total of 10 quantitative studies underwent a more thorough evaluation (see Appendix A, Table A1). With the information collected in the evaluation table, a synthesis table summarizes all the

studies' main data points (see Appendix A, Table A2). The studies used had high levels of evidence, as the majority were meta-analyses, systematic reviews, and RCTs. The mean age of participants in seven studies was 57 years, and three studies did not specify the mean age of participants. The chronic wounds studied primarily included diabetic wounds, venous ulcers, pressure ulcers, or burns.

The intervention for all but one study was PRP through gel, dressings, or injections. Vogt et al. (2020) analyzed sociodemographics against the QoL in patients with chronic wounds rather than investigating the efficacy of PRP on wounds like the other studies. The outcomes and common themes among all the studies were compelling. In six studies, the wound sizes and healing times significantly decreased with the use of PRP. Four studies found evidence that PRP influenced the complete healing of chronic wounds. In addition to PRP efficacy, study results found that PRP had minimal side effects, was safe, and cost-effective. Overall, PRP presents a low risk to patients and promotes healing for complex and persistent wounds of various types.

Theory/Theoretical Framework Application

No two wounds are the same, often requiring a trial-and-error process to determine what works best for each wound. The TIME framework is specific to wounds and provides a holistic approach to assessing and managing chronic wounds (Leaper et al., 2012). The framework helps to better understand the elements that influence wound healing. TIME is widely used in wound care because it provides guidance for preparing the wound bed, improving the efficacy of products and dressings, and enhancing outcomes. TIME stands for tissue assessment and debridement, infection/inflammation, moisture imbalance, and the edge of the wound (Leaper et al., 2012). While the four concepts of TIME focus on ideal wound bed preparation, it is just one piece of the framework (see Appendix B, Figure B1). The TIME components each influence the

wound as a whole; if one is missing, the wound can become compromised. The TIME framework emphasizes the importance of patients' environments and systemic issues like comorbidities, which can also influence wound bed status. When preparing the wound bed, it is imperative to consider product costs, influences on QoL, and the surrounding skin (Leaper et al., 2012). The TIME framework provides a substantial foundation for using PRP on chronic wounds since it proposes a thorough analysis of the entire patient while cultivating an optimal wound bed prior to PRP application, further stimulating proper wound healing.

Implementation Framework

The Model for Improvement: Plan-Do-Study-Act (PDSA) is a quality improvement model that provides a cycle to determine a need for change and a blueprint for implementing and assessing interventions (see Appendix B, Figure B2) (IHI, n.d.-a). The model has a cyclical approach that encourages constant evaluation and reassessment. Before developing a plan, establishing goals, measures, and desired outcomes is paramount (IHI, n.d.-a). The plan consists of clearly stating the goals and determining details related to change execution, who will be involved, and specific data points for outcome measurement. Next, implementation of the plan occurs, and data is collected. After implementation, the data is studied and analyzed. In order to act on the change in a more permanent fashion, it is imperative to make necessary modifications to improve processes with hopes of eventually advancing standard practice. Finally, plans for modifications reinitiate the PDSA cycle. The PDSA model is consistent with the execution of the doctoral project as the project regarding PRP application on chronic wounds is planned, performed, studied, and acted on in a scaffolding fashion throughout the program's remaining semesters.

Implications for Practice Change

Evidence has proven that using PRP on chronic wounds has countless benefits with little to no adverse effects. However, the PRP efficacy data still requires more development, hindering its widespread use. Collecting extensive data points on PRP use and efficacy can influence eventual evidence-based practice changes. A local mobile wound-care organization desires to be innovative and lead the path for change in wound care by implementing and studying the effects of PRP on chronic wounds of various etiologies. After a thorough literature review, PRP use on chronic wounds is primarily used in inpatient and outpatient clinic environments; it has yet to be studied in the mobile setting. Collecting various data points in the mobile setting can present groundbreaking data and results.

The compelling evidence discovered, and the organization's aspirations for innovation have created an opportunity to fill a gap in the literature while improving outcomes for patients with chronic wounds. The stakeholders primarily consist of the nurse practitioners (NPs) applying the PRP when performing wound care. As the NPs chart the wounds, specific data points must be collected for analysis. Data points should include past medical history, wound etiology, time wounds have been open, meticulous measuring, adverse events, and healing time. After data is collected, an analysis will determine PRP efficacy on chronic wounds in the mobile setting. The ultimate goal is to improve wound size and healing time while minimizing adverse events and wound care costs.

Methods

Ethical Considerations

Protecting human subjects throughout the duration of the project was top priority. Prior to beginning the project, the Institutional Review Board at Arizona State University approved the

protocol under an expedited review. Both a written informed consent and HIPAA Authorization Form were signed by all participants.

Population and Setting

Participants were required to be over the age of 18, speak English, have stage III or IV wounds, and receive PRP treatment for their chronic wounds. Participants were excluded from the project if they did not read or speak English, were unable to make medical decisions independently, were unable or unwilling to properly cover dressings while showering or bathing, have an acute osteomyelitis diagnosis, or were currently undergoing wound treatment with skin substitutes. The site champion and NP used clinical judgement to determine which patients were eligible to receive treatment with PRP, while the doctor of nursing practice (DNP) student managed recruitment and screening for potential participants. Since the project site was a mobile clinic, all project visits were performed in patients' residences.

Intervention and Timeline

The project intervention took place during participants regularly scheduled wound care visits. All participants received PRP treatments for a minimum of six weeks unless the NP made the clinical decision to end treatment. At day one of the PRP treatment, the Bates-Jensen Wound Assessment Tool (BWAT) was completed by the DNP student after the wound was cleansed by the NP per the clinic's protocol (See Appendix C). The NP continued to treat the wounds with PRP for the following six weeks. The DNP student attended visits at day one, week three, and week six to collect the BWAT. Not all participants began simultaneously; however, all participants were enrolled for six weeks of treatment on individual timelines.

Data Collection

A substantial amount of data was collected throughout the project's implementation. After participants signed consent, a brief chart review was completed by the DNP student with assistance from the NP. The NP reviewed electronic medical records (EMRs) and shared demographic information with the DNP student, along with additional information about past medical history and wound history (See Appendix D). During the visits at day one, week three, and week six, the BWAT was be completed by the DNP student. The BWAT consists of 13 items related to wound characteristics. The total score was placed on the Wound Status Continuum included in the BWAT, which indicates tissue health, wound regeneration, and wound degeneration. Trending the Wound Status Continuum scores between day one, week three, and week six provided vast information about the effects of PRP on chronic wounds.

Data Analysis

Demographic data collected on the Chart Audit Form was analyzed with descriptive statistics using Intellectus Statistics™ (2023). Descriptive statistics were used to describe the sample and to examine clinical significance of PRP on wound status from BWAT scores at day one, week three, and week six between three wound types (traumatic wound, diabetic wound, and pressure ulcer). One participant did not complete the week six visit, therefore only day one and week three data were used. Two participants completed all three visits.

Budget

All PRP kits and equipment were gifted to the project site by the PRP vendor free of charge. Standard wound supplies that were applied on top of the PRP dressing were the project site's responsibility. The budget plan lists costs for preparation, implementation, and evaluation

of the project and its data (See Appendix E). No grants or scholarships were awarded for the project implementation.

Results

Population

Intellectus Statistics™ (2023) was used to store, analyze, and manage data. Demographic data of the population was collected (see Appendix F, Table F1). The population consisted of three patients (n = 3) that were established with the mobile clinic. Most participants were female (n = 2, 67%) and the remaining participant was male (n = 1, 33%). All subjects were White, non-Hispanic. Two subjects were former smokers (n = 2, 67%) and one subject was a lifetime non-smoker (n = 1, 33%). One subject was currently undergoing UltraMIST® (a cleansing procedure) once per week (n = 1, 33%), while the other two participants did not receive UltraMIST® (n = 2, 67%). All participants had a history of cardiac disease and received oral or topical antibiotics prior to initiation of PRP treatment. The average age of the sample was 69 (*SD* = 9.54) with a range from 63 to 80 (see Appendix F, Table F2).

Laboratory values of all participants were analyzed using descriptive statistics (see Appendix F, Table F3). Intent to treat analysis was required for C-reactive protein and hemoglobin A1c laboratory values for one participant. The average wound stage was 4 (*SD* = 0.58) with a range from 3 to 4. The average hemoglobin A1c was 6 (*SD* = 1.30) with a range from 4.70 to 7.30. The average of prealbumin was 23.37 (*SD* = 12.09) with the minimum of 9.80 and a maximum of 33. White blood count averaged 8.3 (*SD* = 1.81) and ranged from 6.4 to 10. Lastly, C-reactive protein averaged 5.56 (*SD* = 5.01) and ranged from 0.55 to 10.56.

BWAT Scores and Wound Types

The Wound Status Continuum was completed using the BWAT scores and were graphed for each wound type (see Appendix F, Figure 1). The traumatic wound decreased from a score of 24 to 9, indicating complete closure. The diabetic wound scores decreased to 21 from 28, moving closer on the Wound Status Continuum towards wound regeneration. The pressure ulcer degenerated as scores increased from 28 to 29.

BWAT Scores and Smoking Status

Two-thirds (67%) of the participants' wounds improved with PRP treatment. All three participants completed visits at day one and week three. The non-smoker had the most significant improvement in BWAT scores between the two visits with a decrease in 3 points. While the former smokers' BWAT scores decreased from day one to week three, the improvement was less significant and only decreased by 1 point.

BWAT Scores and UltraMIST® Therapy

UltraMIST® System uses low-frequency ultrasound and saline to cleanse wounds and control inflammation to promote wound healing (Sanuwave, n.d.). One subject was receiving UltraMIST® while being concurrently treated with PRP. BWAT scores increased from 28 at day one to 29 at week three, indicating wound degeneration. The other two subjects did not receive UltraMIST® and wounds improved, averaging scores of 26 at day one and 23 at week 3.

Sustainability

Continuing treatment with PRP on chronic wounds within the mobile clinic is highly dependent on equipment availability and NP participation. There were several instances when PRP kits were difficult to obtain from the vendor. Further, while the literature and data prove promising results, only two NPs agreed to trial PRP. If the project site is interested in pursuing

PRP as a treatment option within the mobile clinic, then shipment of PRP kits should be scheduled regularly. In addition, to obtain more data on effectiveness of PRP, more NPs should consider using PRP to treat appropriate wounds. Since PRP kits were gifted to the project site, cost-effectiveness could not be determined. In the future the clinic will be required to purchase kits, which will determine if the treatment is cost-effective.

Discussion

Traumatic Wound

The traumatic wound was the only wound that completely healed. The subject's significant past medical history included hyperlipidemia, hypertension, hyperthyroidism, and former smoker. Hemoglobin A1c and C-reactive protein were not collected for this participant. Prealbumin and white blood count levels were within normal limits. This participant did not receive UltraMIST® while undergoing PRP treatments. The BWAT scores decreased by 15 points between day one and week six, indicating the most significant improvement in wound status compared to the diabetic wound and pressure ulcer.

Diabetic Wound

The participant with the diabetic wound had a past medical history of type 2 diabetes, hypertension, breast cancer, peripheral neuropathy, and heart palpitations. The participant never smoked. Hemoglobin A1c, prealbumin, and C-reactive protein levels were all elevated. The participant did not receive UltraMIST® while being treated with PRP. BWAT scores decreased by 7 points between day one and week six indicating improvement in wound health.

Pressure Ulcer

The subject with the pressure ulcer had a significant history of cardiac disease including congestive heart failure, hypercholesterolemia, myocardial infarct, previous cardiac arrest,

peripheral vascular disease, coronary artery bypass surgery, and was a former smoker. Hemoglobin A1c, white blood count, and prealbumin levels were all within normal limits. C-reactive protein level was elevated. The participant was receiving UltraMIST® once per week while being treated with PRP. The participant expired prior to the week six visit. BWAT scores increased by 1 point between the day 1 visit and the week three visit indicating wound degeneration.

Overall PRP Efficacy

It is imperative to consider patients holistically when assessing effectiveness of PRP treatments on chronic wounds. Past medical history and patients' current health as indicated by laboratory values have a major impact on treatments, wound status, and potential for wound improvement. While two of the three participants experienced improvement with PRP treatments, it is imperative to consider the current health of the participant that experienced wound degeneration. As evidenced by the data collected in this project, PRP had the most significant impact on the traumatic wound. The diabetic wound also responded to PRP treatments; however, it did not completely close like the traumatic wound. The data collected reflects worsening of pressure ulcer wound status with PRP treatments.

Limitations

Limitations were recognized throughout the implementation phase of the project. First, implementation was delayed due to the clinic not having a PRP treatment protocol in place. The NP was required to create a protocol based on the vendor's instructions, which took approximately two months. The NP also had difficulty recruiting participants that qualified for PRP treatments. Only one other NP was willing to administer PRP treatments, which contributed to a small sample size. Shortly after implementation was initiated, the PRP kits expired and there

was a delay in shipment of new PRP kits from the vendor. In addition, multiple subjects missed appointments, which delayed BWAT collections. In some instances, BWATs were not collected exactly at weeks three and six.

Recommendations

PRP is currently used in in- and out-patient settings for aesthetics, orthopedics, and wound care; however, it has not been established in the mobile wound care setting. In order for Centers for Medicare and Medicaid Services (CMS) to create a current procedural technology (CPT) code for reimbursement purposes, more data needs to be collected. Most importantly, PRP has potential to improve wound status leading to decreased healthcare costs, and improved patient outcomes and quality of life. It is recommended that the mobile clinic continue to perform PRP treatments on various wound types and collect data. In order to continue PRP services, the clinic can host a training event for all NPs to increase comfortability with the innovative treatment option. This will allow for more NPs to participate and increase the amount of data collected. With a vast amount of data, the clinic can prove efficacy of PRP on chronic wounds in the mobile setting.

Conclusion

Chronic wounds are complex and challenging to treat. PRP offers a new method to manage and treat wounds, which can change the world of wound care. The literature provides promising evidence for its efficacy in inpatient and outpatient settings; however, its use in the mobile setting has not yet been explored. By setting the foundation with the TIME framework and the Plan-Do-Study-Act model, the project's data provided promising results. The mobile clinic can potentially pioneer a new standard treatment for chronic wounds in the mobile setting. Not only can PRP positively impact patients, but it also can reduce the burden of healthcare costs

in the US diving deeper into the use and efficacy of PRP on chronic wounds in the mobile setting has the power to be revolutionary.

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Appendix A

Evaluation and Synthesis Tables

Table A1

Evaluation Table for Quantitative Studies

Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
Author/Year: Elsaid, et al., 2019 Randomized controlled trial on autologous platelet-rich plasma versus saline dressing in treatment of non-healing diabetic foot ulcers **Country**: Egypt **Funding**: None **Bias**:	Inferred Physiologic Model	**Design:** Prospective RCT open-label **Purpose:** To assess the role of PRP in gel form as a treatment of clean non-healing DFU in comparison with regular dressing with saline as a control	**N=** 24 **Demographics:** **CG:** n = 12, 6 M, 6 F **IG:** n = 12, 8 M, 6 F **Mean age:** 55.2 **Mean HbA1c%:** 7.9 **Mean duration of ulcer:** 5.4 months **Setting:** Outpatient clinic of the General Surgery Department of Mansoura University Hospital **Exclusion:** Chronic limb ischemia; osteomyelitis; exposed tendons,	**IV1:** PRP gel **DV1:** Percent size reduction of DFU **DV2:** Healing of DFU **DV3:** Time to maximal wound healing **Definitions:** Chronicity- non-healing ulcer for 12 or more weeks	**Tools:** No tools were stated for wound measuring **Validity/ Reliability:** Not applicable	**Statistical Tests Used:** Independent sample *t* test, paired sample *t* test, $\chi 2$	**DV1:** PRP group/control group longitudinal: 43.2%/4.1%, $P = 0.001$ PRP group/control group horizontal: 42.3%/8.2%, $P = 0.009$ **DV2:** PRP group: 25% complete healing Control group: 0% complete healing	**Level of Evidence**: II **Strengths**: RCT, no complications, no attrition, adequate sample size, low cost **Weakness**: Open-label, not compared to other standard wound therapies, no specified tools for measuring wounds, wound measuring methods are unknown

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
Open-label study; investigators were aware of the treatment			ligaments, or bones; radio- or chemotherapy within 3 months of study start-up; low platelets, serum albumin, or hemoglobin **Attrition:** 0 lost to follow-up				**DV3:** PRP group: 6.3 weeks Control group: 10.4 weeks	**Feasibility**: Recommended for use in practice for DFU as PRP gel is effective and has low cost **Application**: Applicable for chronic non-healing DFU
Author/Year: Deng, et al., 2022 The efficacy and safety of platelet-rich plasma in the tendon-exposed wounds: A preliminary study **Country**: China **Funding**: None **Bias**:	Inferred Physiologic Model	**Design:** Quantitative preliminary study **Purpose:** To preliminarily evaluate the therapeutic potentials of PRP in such refractory wounds with exposed tendons, as well as corresponding efficacy and safety, so as to	**N=** 12 **Demographics:** 5 males, 7 females **Mean age:** 42.7 **Wound Types:** Traffic accidents (3), contusion (2), burns (2), diabetes complications (4), melanoma complications (1) **Setting:** Admissions to Jiangxi Provincial People's Hospital, The First Affiliated	**IV1:** PRP application **DV1:** VAS scores **DV2:** VSS scores **DV3:** MSS scores **Definitions:** PRP-therapeutic biological product extracted from the venous blood of the body, which contains high concentrations of platelets Refractory wounds-refer to conditions that	**Tools:** VAS, VSS, MSS **Validity/ Reliability:** VAS: highly reliable for assessing pain VSS: poor interobserver reliability, fair intraobserver reliability MSS: good reliability even among different observers No numbers reported	**Statistical Tests Used:** Normality tests, mean & standard deviation analyzed with paired *t* test	**DV1:** Mean VAS pre- was 6.9 & post- was 3.5 **DV2:** Mean VSS pre- was 7.4 & post- was 3.6 **DV3:** Mean MSS pre- was 12.3 & post- was 5.4	**Level of Evidence**: III **Strengths**: PRP is easy to obtain, curative effects of vascular regeneration are reliable, PRP is less technically demanding, provides more treatment options, less invasive than skin flap, no adverse effects

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
None identified		provide a reference for broader clinical applications in the future	Hospital of Nanchang Medical Center **Exclusion:** Severe lesions of large blood vessels with obvious ischemia on Doppler ultrasound, wound too large with exposed bone and/or blood vessels and other wounds requiring skin flaps, severe organ dysfunction, malignant tumors; glucocorticoids, immunosuppressive agents, chemotherapy **Attrition:** 0 lost to follow-up	ulcers that are still difficult to improve, secretion is not reduced, and granulation tissue is not formed after dressing changes and applications of different therapies				**Weakness**: Optimal concentration of PRP is unknown, composition of PRP differs between patients, mechanisms of action are unknown, small sample size, minimal report of reliability and validity of tools used **Feasibility**: Recommended for use due to low cost, no complications, less invasive **Application**: Applicable for a variety of wounds with exposed tendon

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
Author/Year: Xia et al., 2019 The efficacy of platelet-rich plasma dressing for chronic non-healing ulcers: A meta-analysis of 15 randomized controlled trials **Country**: Not specified **Funding**: No funding **Bias**: No bias stated, publication bias was not significant after evaluation	Inferred Physiologic Model	**Design:** Meta-analysis **Purpose:** To summarize the current evidence to evaluate whether superior outcomes can be obtained by using platelet-rich plasma in non-healing ulcers compared with traditional wound care	**N=** 15 randomized trials including 630 adult patients **Demographics:** 252 women, 378 men, average age 61.25, 6 articles with diabetic ulcers, 5 articles with venous ulcers, 4 articles for various refractory ulcers **Setting:** No setting specified **Exclusion:** No original or incomplete data, duplicate publications, postoperative wounds, review articles, letters to editors, editorials, conference abstracts, preclinical studies, acute wounds	**IV:** PRP on non-healing ulcers **CG:** Traditional wound care **DV1:** Chronic ulcers completely healed **DV2:** Number of ulcers healed in weeks 4, 8, & 12 **DV3:** Percentage of wound area healed **DV4:** Healing rate per day **Definitions:** Chronic/non-healing ulcers- traumatic or spontaneous lesions that cannot heal within reasonable amount of time, mostly on extremities PRP- blood products obtained after autologous whole blood concentration and separation, contains platelet concentrations 4-	**Tools:** Cochrane Collaboration's 6-Item Tool for assessing risk of bias Review Manager Software **Validity/ Reliability:** High reliability, recommended tool for Cochrane Reviews 95% confidence rate for Review Manager Software	**Statistical Tests Used:** Chi-squared and $I2$, subgroup analyses	**DV1:** More healed diabetic ulcers in PRP group compared to control group, $p = 0.0003$, no significant differences in venous ulcers **DV2:** Week 4 the # of healed ulcers in PRP group was greater than control group, $p = 0.0002$, difference between the 2 groups was 37.74%; Week 8 # of ulcers in PRP group was greater than control, $p = 0.02$, 23.8% difference; no	**Level of Evidence:** I **Strengths**: Large population size, wide variety of ulcer types, PRP is safe and effective in utilizing growth factors, all studies were RCT, robust data points **Weakness**: Unknown whether patients and assessors were blinded; differing variations like follow-up duration, controls, ulcer duration time,

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
			Attrition: Not applicable	5x higher than whole blood			significant difference at 12 weeks **DV3:** PRP had higher percentage of healed ulcers, $p = 0.02$ **DV4:** Square of healing area per day in PRP group was higher $p < 0.00001$ PRP favored diabetic ulcers	ulcer location, and ulcer measurements; variation in PRP preparation; no standard interval between applications **Feasibility**: PRP is safe, easy to prepare, and has beneficial effects **Application:** More effective for diabetic ulcers compared to venous ulcers
Author/Year: Vogt et al., 2020 Quality of life assessment in chronic wound patients using the Wound-QoL and FLQA-Wk instruments	Inferred Health-Related Quality of Life Model	**Design:** Quantitative study with cross-sectional design **Purpose:** To assess changes in the QoL of	**N=** 100 **Demographics:** Mean age 60.98, 51 male, 53 married, 75 retired, 65 had one wound, 92 patients with lower extremity wounds, 83 were treated for more than 24 months	**IV1:** Sociodemographic (age, sex, education) **DV1:** QoL **DV2:** FLQA-Wk **Definitions:** QoL- an individual's perception of their position in life in the context of the culture and value	**Tools:** Researcher-developed collection for sociodemographic and clinical characteristics; QoL instrument; FLQA-Wk instrument	**Statistical Tests Used:** Descriptive statistics for sociodemographic, descriptive measures for QoL & FLQA-Wk, t-test, Mann Whitney, Spearman's correlation	**DV1:** QoL value of 37.50 (low QoL) **DV2:** FLQA-Wk value of 44.20 (below average)	**Level of Evidence**: III **Strengths**: Valid and reliable tools, questionnaires easy to administer, simple statistics, has implications

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
Country: Brazil **Funding**: None stated **Bias**: None identified, possible bias if assisting participant with answering questionnaire		patients with chronic wounds and compare the average values of the domains of the Wound-QoL and FLQA-Wk with sociodemographic variables	**Setting:** 2 outpatient clinics **Exclusion:** altered cognitive and mental state, no means of communication to answer questions, neoplastic chronic wounds **Attrition:** None noted	systems in which they live and in relation to their goals, expectations, standards, and concerns	**Validity/ Reliability:** Validity/reliability of researcher-developed tool is unknown, no evidence mentioned QoL and FLQA-Wk had Cronbach's Alpha of 0.84 & 0.85 confirming reliable internal consistency	ANOVA, Spearman test	coefficient 0.308 indicates higher the age, the lower the score	for providers with wound care patients **Weakness**: Difficult to determine if lower QoL and higher age is related to general health and treatment; unknown qualifications of professionals assisting with questionnaires for those who need help **Feasibility**: Indicates holistic, patient-centered care for wound patients **Application:** Multidisciplinary teams help the patient as a whole to

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
								streamline care, improve wounds, and improve QoL
Author/Year: Qu et al., 2021 The effectiveness and safety of platelet-rich plasma for chronic wounds: A systematic review and meta-analysis **Country**: United States **Funding**: Agency for Healthcare Research and Quality, US Department of Health and Human Services	Inferred Physiological Model	**Design:** Systematic review and meta-analysis **Purpose:** To evaluate effectiveness and adverse events of autologous PRP in individuals with lower extremity diabetic ulcers, lower extremity venous ulcers, and pressure ulcers	**N=** 25 studies, 1592 patients **Demographics:** 5 studies from Africa, 9 from Asian, 9 from Europe, 2 from US; Diabetic ulcers- 13 RCT, 1 observational Venous ulcers- 6 RCT, 3 observational Pressure ulcers- 1 RCT, 1 observational **Setting:** Not specified **Exclusion:** Traumatic wounds, peripheral artery disease, acute wounds, PRP after skin grafting, in vitro studies, single-arm	**IV:** PRP **CG:** Other wound care excluding PRP **DV1:** Complete wound closure **DV2:** Time to wound closure **DV3:** Wound area **DV4:** Wound depth reduction **Definitions:** Autologous PRP is the fraction of blood plasma from peripheral blood that contains higher than baseline concentrations of platelets with cytokines and growth factors	**Tools:** Cochrane Collaboration's Risk of Bias 2, Newcastle Ottawa Scale **Validity/ Reliability:** High reliability, recommended tool for Cochrane Reviews for RCTs	**Statistical Tests Used:** Calculated relative risk, weighted mean difference, DerSimonian-Laird random effect model with Hartung-Knapp-Sidik-Jonkman variance correction, fixed effect, heterogeneity, funnel plots and Egger's regression, two-tailed *P* values	**DV1:** Moderate strength of evidence of diabetic ulcers; insufficient evidence for venous **DV2:** Shorter time with low strength of evidence for diabetic **DV3:** More wound area with low strength of evidence for diabetic; insufficient evidence for venous	**Level of Evidence**: I **Strengths**: Statistically complex yielding valuable data, large population size, high level of evidence, many checks and balances, variety of wound types **Weakness**: Statistically complex, insufficient evidence for many outcomes, sample size possibly too large **Feasibility**: Evidence does

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Bias: Included studies have moderate to high risk of bias			observational studies, case studies, non-English studies **Attrition:** None				**DV4:** Wound depth reduction with low strength of evidence for diabetic	not prove efficacy of PRP on chronic wounds **Application:** No significant adverse events, however, little benefit for use of PRP on most chronic wounds
Author/Year: Elbarbary et al., 2020 Autologous PRP plasma injection enhances healing of chronic venous leg ulcer: A prospective randomized study **Country**: Egypt **Funding**: Not stated	Inferred Physiological Model	**Design:** Prospective randomized study **Purpose:** To evaluate efficacy of PRP application versus PRP injection for treatment of chronic venous leg ulcers	**N=** 90 **Demographics:** **CG:** n = 30, 24 males, **IG1:** n = 30, 26 males, **IG2:** n = 30, 22 males **Mean age:** **CG:** 41.8 years **IG1:** 45.4 years **IG2:** 43.4 years **Setting:** outpatient clinic & vascular surgery department	**IV1:** PRP application **IV2:** PRP injection **DV1:** Ulcer reduction **DV2:** Ulcer complete healing rate **DV3:** Ulcer recurrence **DV4:** Safety **Definitions:** None specified	**Tools:** Ulcer tracking technique **Validity/ Reliability:** High reliability since ulcer measurement was standardized for each ulcer by delineating wound edge and measuring with 1 cm2 squares for accuracy and consistency	**Statistical Tests Used:** Data analyzed using version 26 of IBM SPSS, parametric for mean and standard deviation, nonparametric for median and range, ANOVA for differences among groups, Shapiro-Wilks test to verify distribution normality, $P < .05$	**DV1:** CG: 52% at 3 months, 69% at 6 months, 78.6% at 12 months IG1: 65% at 3 months, 92% at 6 months, 92.7% at 12 months $P = .015$ (3 months), .001 (6 months), <.001 (12 months)	**Level of Evidence**: II **Strengths**: All groups with same population size, consistency in wound measurement, same types of ulcers for entire study, consistency is PRP collection methods and dressing types, the person measuring

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Bias: No biases identified			**Exclusion:** renal/hepatic/cardiac failure, uncontrolled diabetes, malignancy, connective tissue disorder, pregnancy, lactation, active infection, bone or tendon exposure, antiplatelets/steroids or immunosuppressives, inability to give consent **Attrition:** None			indicated significance	**DV2:** CG: 46.7% IG1: 66.7% IG2: 80% *P* = .007 **DV3:** 7.8% of total ulcers completely closed, no significant difference between groups, *P* = .326 **DV4:** CG: cellulitis 7.6% IG1: 1/30 superficial minute ulcer IG2: cellulitis 7.6%, superficial minute ulcer 1/30	wounds was blinded to groups **Weakness**: Most recurrences due to non-compliance with compression therapy **Feasibility**: PRP injection is most effective in healing chronic venous ulcers, PRP application is more effective than compression therapy alone **Application:** PRP injection and application to be used on chronic venous ulcers

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Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
Author/Year: Kao et al., 2021 Assisten therapy with platelet-rich plasma for burn patients: A meta-analysis and systematic review **Country**: Taiwan **Funding**: Not specified **Bias**: Included studies have varying degrees of bias	Inferred Physiological Model	**Design:** Meta-analysis and systematic review **Purpose:** Evaluate the safety and efficacy of PRP treatment on burn wounds	**N=** 8 studies, 449 patients **Demographics:** 6 RCTs, 2 retrospective studies **Mean follow-up:** 3-4 months **Wound degree:** 2nd degree wound (3), deep 2nd and 3rd degree wound (2), chemical ocular (2), unspecified degree (1) **Setting:** Not specified **Exclusion:** Not English or Chinese language, nonhuman participants, no focus on wound healing, case reports & case series **Attrition:** None	**IV1:** PRP application **DV1:** Time to complete epithelialization **DV2:** Wound closure rates at 2 & 3 weeks **DV3:** Post-operative infection rates **DV4:** Graft take rate **Definitions:** None specified	**Tools:** Cochrane Risk of Bias tool Newcastle-Ottawa Scale **Validity/ Reliability:** Reliable, used to assess bias in RCTs, uses 6 domains to assess bias Reliable for determining methodological quality using a rating system, appropriate for RCTs	**Statistical Tests Used:** Review Manager for statistical analysis, odds ratios & 95% confidence intervals for categorical variables, I2 for heterogeneity, p <0.05 for statistical significance	**DV1:** PRP had significantly shorter time [95% CI: -4.87, -2.04], I2: 0%, p <0.00001 **DV2:** PRP had significant difference compared to control groups at 2 weeks [95% CI: 7.08, 18.49], I2: 0%, p <0.0001 and 3 weeks [95% CI: 5.97, 19.34], I2: 55%, p = 0.0002 **DV3:** No significant difference, p = 0.09	**Level of Evidence**: I **Strengths**: Only high quality studies were included after analysis by 2 independent reviewers, reliable tools used for inclusion **Weakness**: Varying biases depending on the included studies, small sample size, varying wound types, variation in PRP collection, variation in wound measurement **Feasibility**: PRP application provides benefits to burn wounds

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							DV4: No significant difference, $p = 0.27$	of different stages with low risk **Application:** PRP application on burn wounds

Key: **CG** Control Group, **CI** Confidence Interval, **DFU** Diabetic Foot Ulcers, **DV** Dependent Variable, **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version, **IG** Intervention Group, **IV** Independent Variable, **MSS** Manchester Scar Scale, **PRP** Platelet-Rich Plasma, **PUSH** Pressure Ulcer Scale for Healing, **QoL** Quality of Life, **RCT** Randomized Controlled Trial, **VAS** Visual Analog Scale, **VSS** Vancouver Scar Scale

Author/Year: del Pino-Sedeño et al., 2019 Platelet-rich plasma for the treatment of diabetic foot ulcers: A meta-analysis **Country**: Spain **Funding**: Not specified **Bias**: Included studies have varying degrees of bias	Inferred Physiological Model	**Design:** Systematic review and meta-analysis **Purpose:** Evaluate the safety and efficacy of PRP for treatment of DFUs compared to standard or alternative therapies	**N=** 10 studies, 525 participants **Demographics:** **CG:** Standard or alternative therapy **IG:** PRP **Study types:** 8 RCTs, 2 prospective longitudinal-observational **Mean age:** 57.98 years **Gender:** 43% women **Setting:** Not specified **Exclusion:** Other wound types, no restrictions on publication date or languages **Attrition:** 48 lost to follow-up	**IV1:** PRP **DV1:** Wound healing/epithelialization **DV2:** Volume of ulcer **DV3:** Complete wound healing **DV4:** Safety **DV5:** Recurrences **DV6:** Rate of adverse events **Definitions:** None specified	**Tools:** Cochrane Collaboration's tools Grading of Recommendations Assessment, Development, and Evaluation (GRADE) **Validity/ Reliability:** Reliable, used to assess bias in RCTs, uses 6 domains to assess bias Good reliability, uses 5 domains to assess quality/certainty of evidence	**Statistical Tests Used:** Review Manager version 5.3, Mantel-Haenszel method, mean difference, heterogeneity, DerSimonian and Laird method, meta regression methods	**DV1:** No increase in epithelialized area, $p = 0.41$ **DV2:** Significantly decreased volume of ulcer, $p < 0.01$ **DV3:** PRP significantly decreased time to heal, $p = 0.02$ **DV4:** No differences in rates of wound complications, $p > 0.01$ **DV5:** No differences in rates of recurrences, $p = 0.43$ **DV6:** PRP decreased rate of adverse events, $p = 0.02$	**Level of Evidence**: I **Strengths**: Same wound type in all studies **Weakness**: No clear exclusion criteria, different PRP collection protocols, different PRP substances used, different frequency of PRP application, 7/10 studies had high risk of bias in at least one domain, wound measuring techniques varied, different dressing types, homogeneity decreased significantly with removal of one study **Feasibility**: Indicates benefits to PRP on diabetic wounds with minimal risks

Key: **CG** Control Group, **CI** Confidence Interval, **DFU** Diabetic Foot Ulcers, **DV** Dependent Variable, **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version, **IG** Intervention Group, **IV** Independent Variable, **MSS** Manchester Scar Scale, **PRP** Platelet-Rich Plasma, **PUSH** Pressure Ulcer Scale for Healing, **QoL** Quality of Life, **RCT** Randomized Controlled Trial, **VAS** Visual Analog Scale, **VSS** Vancouver Scar Scale

Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
								Application: For DFU
Author/Year: Tian et al., 2019 Application of standardized PRP in elderly patients with complex wounds **Country**: China **Funding**: National Natural Science Foundation of China, National Key Research and Development Plan of China, National Basic Science and Development Program, Health & Medical	Inferred Physiological Model	**Design:** Case control study **Purpose:** To develop a standardized method for PRP preparation	**N=** 21 **Demographics:** **Gender:** 12 females **Mean age:** 68.3 years **Setting:** Not specified **Exclusion:** Cancer, connective-tissue disease, immunodeficiency disorders, mental disorders, serious cardiac diseases, infections, coagulation defects, platelets <100 x 10^6/L, hemoglobin concentration <110 g/L **Attrition:** None	**IV1:** Standardized PRP prep with centrifugation twice **DV1:** Platelet count/platelet indices **DV2:** Wound healing time **Definitions:** PRP: The plasma fraction from whole blood with a supra-physiologic concentration of platelets	**Tools:** No tools specified, measuring tools/techniques was not identified **Validity/ Reliability:** N/A	**Statistical Tests Used:** mean and standard deviation for platelet indices, paired sample *t*-tests, $p <$ 0.05 indicated significance, SPSS v21	**DV1:** Platelet count increased from 219 in whole blood to 1,218 after 2nd centrifugation, $p <$0.05 **DV2:** Accelerated healing after PRP prep (no statistical values proving this)	**Level of Evidence**: III **Strengths**: Clear outline of how PRP prep was done including measurements, centrifuge settings, and required platelet counts for samples; formulas for platelet concentration included **Weakness**: Statistical results for efficacy were not presented , large controlled pilot study needed to confirm results

Key: **CG** Control Group, **CI** Confidence Interval, **DFU** Diabetic Foot Ulcers, **DV** Dependent Variable, **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version, **IG** Intervention Group, **IV** Independent Variable, **MSS** Manchester Scar Scale, **PRP** Platelet-Rich Plasma, **PUSH** Pressure Ulcer Scale for Healing, **QoL** Quality of Life, **RCT** Randomized Controlled Trial, **VAS** Visual Analog Scale, **VSS** Vancouver Scar Scale

Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
Treatment Collaborative Innovation Major Special Projects of Guangzhon, Science & Technology Planning Project of Guangdong Province of China, Science and Technology Key Project of Guangdong Province **Bias**: None identified								**Feasibility**: Cost-effective and time-efficient **Application:** Standardized PRP prep increases consistency in PRP therapy for complex wounds, increases outcomes, and does not present side effects
Author/Year: Uçar et al., 2020 Comparison of PRP gel in the care of the pressure ulcers with the dressing with serum	Inferred Physiological Model	**Design:** Prospective RCT **Purpose:** Compare effects of PRP gel and gas dressing with serum physiologic applied to stage II	**N=** 60 **Demographics:** **CG:** 52.4% female **IG:** 47.6% femlae **Mean age:** **CG:** 67.8 years **IG:** 68.3 years	**IV1:** PRP gel **CG:** Serum physiological gas dressing **DV1:** Wound size **DV2:** Exudate amount	**Tools:** Barthel Daily Living Activities Scale, Glaskow Coma Scale, PUSH **Validity/ Reliability:**	**Statistical Tests Used:** SPSS 15 package, Kolmogorov-Smirnov test, *t*-test, Nonparametric Mann Whitney *U* test,	**DV1:** **IG:** Decreased 4.7 ro 2.83, p =.001 **CG:** Increased 4.83 to 5.0, p =.166	**Level of Evidence**: II **Strengths**: All dressings performed by the researcher for consistency, all wounds measured using

Key: **CG** Control Group, **CI** Confidence Interval, **DFU** Diabetic Foot Ulcers, **DV** Dependent Variable, **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version, **IG** Intervention Group, **IV** Independent Variable, **MSS** Manchester Scar Scale, **PRP** Platelet-Rich Plasma, **PUSH** Pressure Ulcer Scale for Healing, **QoL** Quality of Life, **RCT** Randomized Controlled Trial, **VAS** Visual Analog Scale, **VSS** Vancouver Scar Scale

Citation	Theoretical/ Conceptual Framework	Design/ Method/ Purpose	Sample/Setting	Variables	Measurement/ Instrumentation	Data Analysis	Results/ Findings	Level of Evidence; Application to practice; Generalization
physiology in terms of healing process and dressing costs **Country**: Turkey **Funding**: Zonguldak Bulent Ecevit University Scientific Research Projects Unit, Grant: 2018-19093093-01 **Bias**: None identified		pressure ulcer in coccyx for 2 months on healing process and dressing costs	**Setting:** inpatient palliative care unit post-surgery **Exclusion:** Impaired renal function, albumin, platelets, blood glucose, limited mobility; non-Turkish literacy, wounds other than coccyx stage II, immunodeficiency **Attrition:** None	**DV3:** Tissue type **Definitions:** Serum physiological gas dressing is a method that prevents the entry of external microorganisms into the wound that protects the moisture of the wound, but cannot provide antiseptic properties	Turkish validity and reliability of Barthel's published in 2000; reliability and validity coefficient for this study was 0.95 Glaskow Coma Scale is reliable and valid as it is used widely to determine level of consciousness PUSH is used frequently in Turkey, but validity and reliability has not yet been determined	Nonparametric Wilcoxon test, Chi-square and Fisher's exact test, p <0.05 indicates significance	**DV2:** **IG:** Decreased 1.93 to 0.93, p =.001 **CG:** Decreased 2.17 to 1.93, p =.115 **DV3:** **IG:** Decreased 1.87 to 1.2, p =.001 **CG:** Increased 1.87 to 1.97, p =.366	the same camera and disposable rulers **Weakness**: Unknown reliability of PUSH **Feasibility**: Easily accessible and low cost **Application:** PRP gel is effective in treating stage II coccyx pressure ulcers

Key: **CG** Control Group, **CI** Confidence Interval, **DFU** Diabetic Foot Ulcers, **DV** Dependent Variable, **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version, **IG** Intervention Group, **IV** Independent Variable, **MSS** Manchester Scar Scale, **PRP** Platelet-Rich Plasma, **PUSH** Pressure Ulcer Scale for Healing, **QoL** Quality of Life, **RCT** Randomized Controlled Trial, **VAS** Visual Analog Scale, **VSS** Vancouver Scar Scale

Table A2

Synthesis Table

Study (Author, year)	del Pino-Sedeño et al., 2019	Deng et al., 2022	Elbarbary et al., 2020	Elsaid, et al., 2019	Kao et al., 2021	Qu et al., 2021	Tian et al., 2019	Uçar et al., 2020	Vogt et al., 2020	Xia et al., 2019
Design LOE	SR/MA I	Quantitative preliminary III	RCT II	RCT II	SR/MA I	SR/MA I	Case control III	RCT II	Quantitative with cross-sectional III	Meta-analysis I
Sample										
n subjects	10 studies	12	90	24	449	1592	21	60	100	630
M-Age	58	43	44	55	Not stated	Not stated	68	68	61	Not stated
Diabetic wound	X	X		X						X
Venous ulcer			X							X
Pressure ulcer								X		
Burn		X			X					
Other		X				X	X		X	X
Setting										
Inpatient		X						X		
Outpatient			X	X					X	
Unknown	X				X	X	X			X
Interventions										
PRP gel/dressing	X	X	X	X	X	X		X		X
PRP injection			X							
Sociodemographics									X	
PRP centrifuge x2							X			
Outcomes/ Themes										
Wound size	↓		↓	↓	↓	↓		↓		
Healing time	↓		↓	↓		↓		↓		↓
Complete healing				↑	↑	↑				↑
Number healed	↑		↑		↑					↑
Exudate amount								↓		↑
QoL & FLQA-Wk									↓	

Key: **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version **LOE** Level of Evidence **M-Age** Mean Age **MA** Meta-Analysis **MSS** Manchester Scar Scale **PRP** Platelet-Rich Plasma **QoL** Quality of Life **SR** Systematic Review **VAS** Visual Analog Scale **VSS** Vancouver Scar Scale

Study (Author, year)	del Pino-Sedeño et al., 2019	Deng et al., 2022	Elbarbary et al., 2020	Elsaid, et al., 2019	Kao et al., 2021	Qu et al., 2021	Tian et al., 2019	Uçar et al., 2020	Vogt et al., 2020	Xia et al., 2019
Safety	↑	↑				↑	↑			↑
Cost-effective	↑	↑	↑		↑	↑		↑		↑
Platelet count		↑		↑			↑	↑		
VAS		↓					↑	↑		
VSS		↓								
MSS		↓								

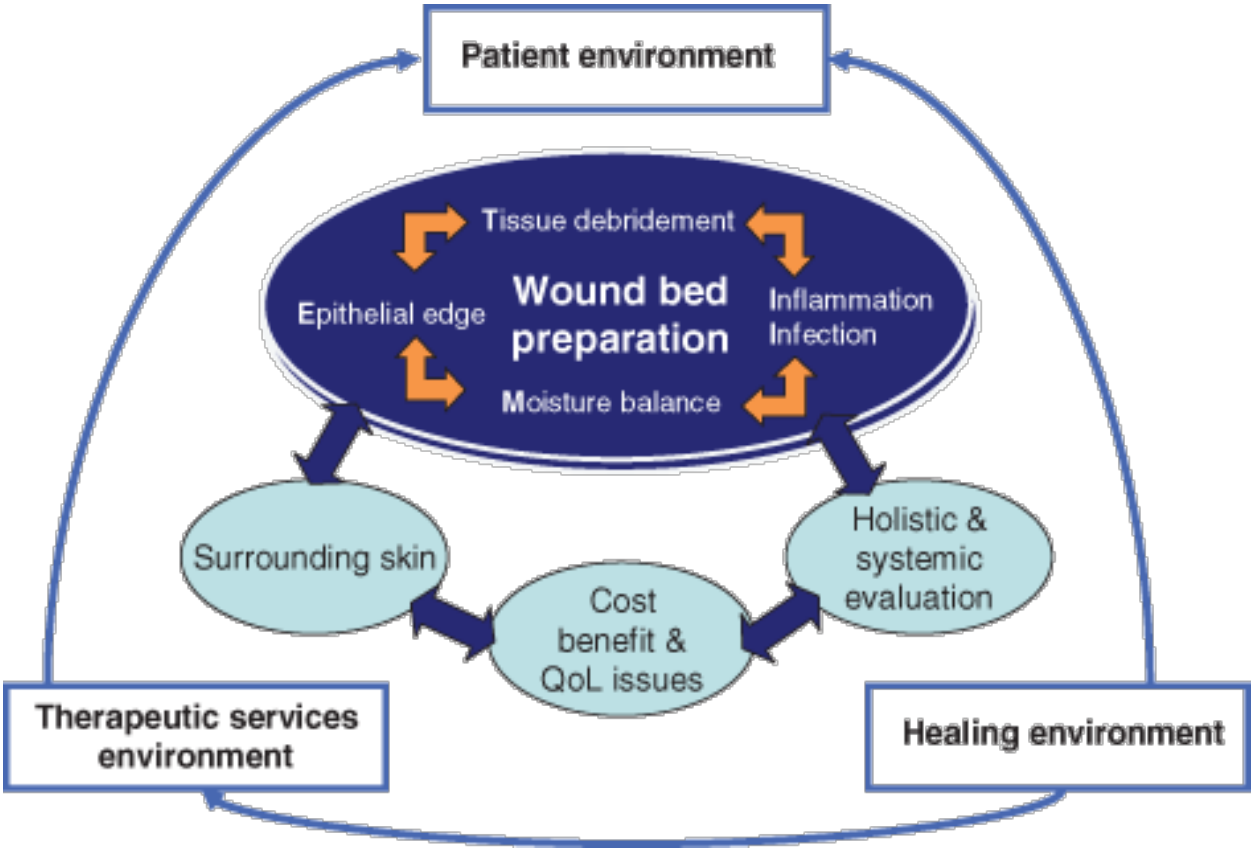
Key: **FLQA-Wk** Freiburg Life Quality Assessment Wound – Wound Version **LOE** Level of Evidence **M-Age** Mean Age **MA** Meta-Analysis **MSS** Manchester Scar Scale **PRP** Platelet-Rich Plasma **QoL** Quality of Life **SR** Systematic Review **VAS** Visual Analog Scale **VSS** Vancouver Scar Scale

Appendix B

Models and Frameworks

Figure B1

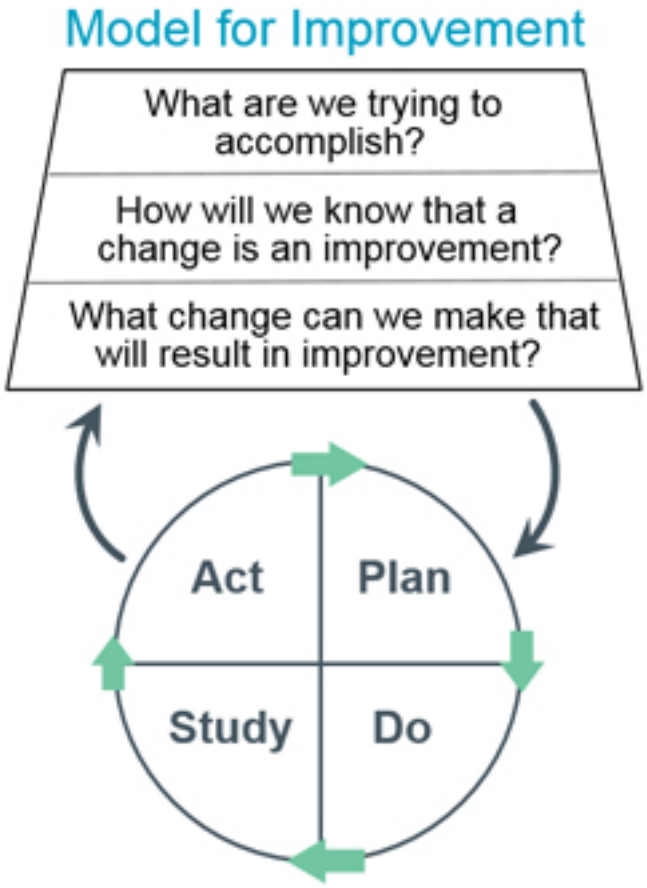
The TIME Framework



(Leaper et al., 2012)

Figure B2

Model for Improvement: Plan-Do-Study-Act (PDSA)



(IHI, n.d.-a)

Appendix C

BATES-JENSEN WOUND ASSESSMENT TOOL NAME

Complete the rating sheet to assess wound status. Evaluate each item by picking the response that best describes the wound and entering the score in the item score column for the appropriate date. If the wound has healed/resolved, score items 1,2,3, & 4 as =0.

Location: Anatomic site. Circle, identify right **(R)** or left **(L)** and use **"X"** to mark site on body diagrams:

___ Sacrum & coccyx ___ Lateral ankle
___ Trochanter ___ Medial ankle
___ Ischial tuberosity ___ Heel
___ Buttock ___ Other site: _____.

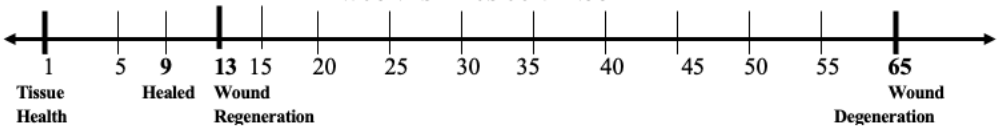
Shape: Overall wound pattern; assess by observing perimeter and depth.
Circle and date appropriate description:

___ Irregular ___ Linear or elongated
___ Round/oval ___ Bowl/boat
___ Square/rectangle ___ Butterfly Other Shape

Item	Assessment	Date Score	Date Score	Date Score
1. Size*	*0 = Healed, resolved wound 1 = Length x width <4 sq cm 2 = Length x width 4--≤16 sq cm 3 = Length x width 16.1--≤36 sq cm 4 = Length x width 36.1--≤80 sq cm 5 = Length x width >80 sq cm			
2. Depth*	*0 = Healed, resolved wound 1 = Non-blanchable erythema on intact skin 2 = Partial thickness skin loss involving epidermis &/or dermis 3 = Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/or mixed partial & full thickness &/or tissue layers obscured by granulation tissue 4 = Obscured by necrosis 5 = Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures			
3. Edges*	*0 = Healed, resolved wound 1 = Indistinct, diffuse, none clearly visible 2 = Distinct, outline clearly visible, attached, even with wound base 3 = Well-defined, not attached to wound base 4 = Well-defined, not attached to base, rolled under, thickened 5 = Well-defined, fibrotic, scarred or hyperkeratotic			
4. Under-mining*	*0 = Healed, resolved wound 1 = None present 2 =Undermining < 2 cm in any area 3 = Undermining 2-4 cm involving < 50% wound margins 4 = Undermining 2-4 cm involving > 50% wound margins 5 = Undermining > 4 cm or Tunneling in any area			
5. Necrotic Tissue Type	1 = None visible 2 = White/grey non-viable tissue &/or non-adherent yellow slough 3 = Loosely adherent yellow slough 4 = Adherent, soft, black eschar 5 = Firmly adherent, hard, black eschar			
6. Necrotic Tissue Amount	1 = None visible 2 = < 25% of wound bed covered 3 = 25% to 50% of wound covered 4 = > 50% and < 75% of wound covered 5 = 75% to 100% of wound covered			

Item	Assessment	Date Score	Date Score	Date Score
7. Exudate Type	1 = None 2 = Bloody 3 = Serosanguineous: thin, watery, pale red/pink 4 = Serous: thin, watery, clear 5 = Purulent: thin or thick, opaque, tan/yellow, with or without odor			
8. Exudate Amount	1 = None, dry wound 2 = Scant, wound moist but no observable exudate 3 = Small 4 = Moderate 5 = Large			
9. Skin Color Sur-rounding Wound	1 = Pink or normal for ethnic group 2 = Bright red &/or blanches to touch 3 = White or grey pallor or hypopigmented 4 = Dark red or purple &/or non-blanchable 5 = Black or hyperpigmented			
10. Peripheral Tissue Edema	1 = No swelling or edema 2 = Non-pitting edema extends <4 cm around wound 3 = Non-pitting edema extends >4 cm around wound 4 = Pitting edema extends < 4 cm around wound 5 = Crepitus and/or pitting edema extends >4 cm around wound			
11. Peripheral Tissue Induration	1 = None present 2 = Induration, < 2 cm around wound 3 = Induration 2-4 cm extending < 50% around wound 4 = Induration 2-4 cm extending > 50% around wound 5 = Induration > 4 cm in any area around wound			
12. Granu-lation Tissue	1 = Skin intact or partial thickness wound 2 = Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth 3 = Bright, beefy red; < 75% & > 25% of wound filled 4 = Pink, &/or dull, dusky red &/or fills ≤ 25% of wound 5 = No granulation tissue present			
13. Epithe-lializa-tion	1 = 100% wound covered, surface intact 2 = 75% to <100% wound covered &/or epithelial tissue extends >0.5cm into wound bed 3 = 50% to <75% wound covered &/or epithelial tissue extends to <0.5cm into wound bed 4 = 25% to < 50% wound covered 5 = < 25% wound covered			
	TOTAL SCORE			
	SIGNATURE			

WOUND STATUS CONTINUUM



Plot the total score on the Wound Status Continuum by putting an **"X"** on the line and the date beneath the line. Plot multiple scores with their dates to see-at-a-glance regeneration or degeneration of the wound.

Appendix D

Chart Audit Form

Subject ID	AGE (YEARS)	GENDER 1 Male 2 Female 3 Other (write in)	RACE 1 American Indian/Alaskan Native 2 Asian 3 Black/African American 4 Native Hawaiian or Other Pacific Islander 5 White 6 Other	ETHNICITY 1 Hispanic or Latino 2 Not Hispanic or Latino	SMOKING 1 Current 2 Former 3 Non-smoker 4 Vape	ALLERGIES	PMH 1 T2D 2 HTN 3 Obesity 4 CKD 5 Liver disease 6 PVD 7 DVT hx 8 Other cardiac disease	ABX (TYPE & DATE)	WOUND TYPE 1 Diabetic ulcer 2 Pressure ulcer 3 Traumatic 4 Venous ulcer 5 Other	WOUND STAGE 1 III 2 IV	ONSET (write in)
100											
101											
102											
103											
104											
105											
106											
107											
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109											
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118											
119											
120											
121											
200											
201											

Appendix E

Budget

Phase	Activities	Cost	subtotal	Total
Preparation	Print Bates-Jensen Wound Assessment Tool ($0.05/page x 30 pages)	$1.50		
	Print written informed consents and HIPAA form ($0.05/page x 30 pages)	$1.50		
	Print recruitment flyers ($0.05/page x 30 pages)			
	Locking storage file box	$39.99		
	Microsoft Office	$34.99	$77.98	
Delivery	Gas ($3.95/gallon)	$63.20		
	Masks	$9.99	$73.19	
Evaluation	Intellectus	$80		
	Statistician	$300	$380	**$531.17**
Cost Versus Revenue/Savings	Reduction in unnecessary wound care dressings and procedures			
	Reduction in wound-related complications and hospitalizations			

Appendix F

Table F1

Frequency Table for Demographics

Variable	*n*	*%*
Gender		
Male	1	33.33
Female	2	66.67
Smoking Status		
Former	2	66.67
Non-smoker	1	33.33
UltraMIST®		
Yes	1	33.33
No	2	66.67
Past Medical History		
Cardiac disease + peripheral vascular disease	1	33.33
Cardiac disease + hypertension	1	33.33
Cardiac disease + type 2 diabetes	1	33.33
Prior Antibiotics		
Custom lipogel & oral antibiotics	1	33.33
Custom lipogel	1	33.33
Custom lipogel, oral & topical antibiotics	1	33.33

Table F2

Summary Statistics Table for Age

Variable	*M*	*SD*	*n*	Min	Max
Age (years)	69.00	9.54	3	63.00	80.00

Note. 'M' signifies the mean. 'SD' is the standard deviation. 'n' is the sample size. 'Min' and 'Max' represent the range.

Table F3

Frequency Table for Laboratory Values

Variable	*M*	*SD*	*n*	Min	Max
Wound stage	3.67	0.58	3	3.00	4.00
Hemoglobin A1c (%)	6.00	1.30	3	4.70	7.30
Prealbumin (mg/dL)	23.37	12.09	3	9.80	33.00
White blood count (microliters)	8.30	1.81	3	6.40	10.00
C-reactive protein (mg/L)	5.56	5.01	3	0.55	10.56

Note. 'M' signifies the mean. 'SD' is the standard deviation. 'n' is the sample size. 'Min' and 'Max' represent the range.

Figure 1

Bates-Jensen Wound Assessment Tool Scores for Wound Types